BACKGROUND

Historically, the federal government has proposed and implemented guidelines, policies, rules and regulations which establish standards for the conduct of higher education personnel and programs funded with public funds. One of the recent issues to affect most universities pursuing sponsored research projects is conflicts of interest.

Several federal agencies have issued guidelines that grantees must abide by if external funding is to be utilized. These guidelines have shaped University policy and procedures regarding financial conflicts of interest in relation to sponsored activities involving research, education, and services. Their purpose is to protect the credibility and integrity of Southwestern Oklahoma State University’s faculty and staff in order that the public trust and confidence in all sponsored activities is ensured.

These regulations require that principal investigators disclose to the designated university official certain significant financial interests that would reasonably appear to be affected by the proposed sponsored activity. These disclosures must be submitted at or before the time of submission of the proposed application for funding. Based on the disclosed information, the university is held responsible for determining whether a conflict of interest exists.

A potential conflict of interest exists when there is a divergence between an individual’s private interests and his or her professional obligations to the University such that an independent observer might reasonably question whether the individual’s professional actions or decisions are determined by considerations of personal gain, financial or otherwise. An actual conflict of interest depends on the situation and not on the character or actions of the individual.

For purposes of this policy, a conflict of interest exists when the university reasonably determines that a significant financial interest (SFI) could directly or indirectly and significantly affect the design, conduct, or reporting of the sponsored activities.

The University must report to the sponsoring agency related to the existence of conflicts and maintain records of financial disclosures and actions taken as part of the project’s history in compliance with OMB circular A-110. In addition, the guidelines require that all financial disclosures be updated during the award period, and be reported on an annual basis or as new significant financial interests are discovered. The final component of the required policy is to establish adequate enforcement mechanisms and to provide sanctions where appropriate.

U.S. Public Health Service Regulation

As of August 25, 2012, the University is required to develop and implement a plan to manage, reduce, or eliminate the conflict of interest in accordance with the 2011 Revised Financial Conflict of Interest (FCOI) Regulation, Promoting Objectivity in Research (42 CFR Part 50 Subpart F). This regulation applies to all U.S. Public Health Service (PHS) grants and contracts including those from the National Institutes of Health (NIH).

Under this regulation, the University is required to make certain information available concerning identified Financial Conflicts of Interest (FCOIs) held by senior/key personnel via a publicly accessible website or by a written response to any requestor within five business days of a request, and update such information as specified in the rule. The website will be updated at least annually with newly identified FCOI to be included within 60 days. This information will include, at a
minimum, the investigator’s name; the investigator’s title and role with respect to the research project; the name of the entity in which the SFI is held; the nature of the SFI; and the approximate dollar value of the SFI, or a statement that the interest is one whose value cannot be readily determined through reference to public prices or other reasonable measures of fair market value.

Each investigator must complete FCOI training prior to engaging in research related to any PHS-funded grant or contract and at least every four years, and immediately under the circumstances such as:

- Institutional FCOI policies change in a manner that affects investigator requirements;
- An investigator is new to an institution;
- An institution finds an investigator noncompliant with its FCOI policy or management plan; and
- Training is provided on request as described in the Managing Conflicts of Interest Training Plan for U.S. Public Health Service Related Grants and Contracts.

The Office of Sponsored Programs will maintain records of FCOI training related to PHS grants and contracts.

**DEFINITIONS**

The term **investigator** means the principal investigator, co-principal investigator, and any other person at the institution who is responsible for the design, conduct, or reporting of a sponsored activity funded or proposed for funding by an external sponsor.

**For PHS funded grants and contracts (including NIH programs) the term investigator means the principal investigator stated in the application and any other personnel who would be responsible for the design, conduct, or reporting of research funded by the PHS agency or proposed for such funding, which may include, for example, consultants and unpaid collaborators.**

**Sponsored activities** include research, research consultation, teaching, professional practice, institutional committee memberships, and service on panels such as institutional review boards or data and safety monitoring boards funded by an external sponsor.

A **significant financial interest** is defined as anything of **monetary value** received directly or indirectly from a sponsor in excess of **$5,000** or ANY ownership interest for the investigator, his or her spouse, and dependent children combined.

The **monetary value** can include, but is not limited to:

1. Salary or other payments for services such as consulting fee and honoraria;
2. Equity interests such as stocks, stock options, or other ownership interests;
3. Intellectual property rights such as patents, copyrights, and royalties from such rights; and
4. Disclosure of any occurrence of ANY reimbursed or sponsored travel: With respect to reimbursed or sponsored travel, investigators will need to report. at a minimum, the purpose of the trip, identity of the sponsor/organizer, destination, and duration. This information must be reported to the institution once reimbursement/travel expenses reach the **de minimus** threshold of $5,000 from a single entity.

Significant financial interests do **NOT** include:

1. Salaries, royalties, or other compensation from the applicant’s institution;
2. Ownership interests in the applicant’s institution, if the institution is an applicant under the SBIR program or Small Business Technology Program for NSF;

3. Combined income from seminars, lectures, or teaching engagements sponsored by and service on advisory or review panels for a federal, state, or local U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of Higher Education;

4. Excludes 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;

5. Travel that is reimbursed or sponsored by a federal, state, or local government agency, an Institution of Higher Education as defined at 20 U.S.C. § 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of Higher Education. The institution will determine if any travel requires further investigation, including determination or disclosure of the monetary value.

6. Salary, royalties, or other payments that when aggregated for the investigator and the investigators spouse and dependent children over the next 12 months are not expected to exceed $5,000 and does not represent ANY ownership interest in a single entity.

**POLICY**

It is the policy of SWOSU that the investigator(s) must disclose any significant financial interests that would reasonably appear to directly or indirectly and significantly affect the design, conduct, or reporting of sponsored activities funded or proposed for funding by an external sponsoring agency.

**DISCLOSURE REQUIREMENTS**

Investigators must file disclosures of significant financial interests and any required documentation to the designated university official prior to submitting proposals to an external sponsoring agency.

**For PHS funded grants and contracts any person who would be responsible for the design, conduct, or reporting of research funded by the PHS or proposed for such funding, including but not limited to consultants and unpaid collaborators are required to disclose FCOI.**

*Timing of Reporting: If a financial interest is identified during the course of the project that is determined to be an FCOI, the institution must report it to the agency as required by the regulations.*

**A Financial Conflict of Interest Disclosure Form has been developed for this purpose. This disclosure will be treated as confidential information and used only for compliance with federal regulations regarding conflicts of interest.**

Records of investigator(s) financial disclosures, any required documentation, and actions taken to manage conflicts of interest shall be retained for three years following the termination or completion of the award to which they relate, or the resolution of any government action involving those records, whichever is longer.

**DISCLOSURE REVIEW**

Disclosures shall be reviewed by the designated university official prior to submitting the proposal or, in cases where the grant or contract has already been awarded, prior to initiating expenditures from grants, contracts, or cooperative agreements awarded by the sponsoring agency. The designated university official will determine whether a conflict of interest exists and how such conflicts may be managed, reduced, or eliminated.
In cases where conflicts of interest are identified, the designated university official will have the responsibility for developing a plan, acceptable to both the investigator and the university, to manage, reduce, or eliminate the conflict of interest. No funds will be expended prior to the development of this plan. For new conflicts that arise during an active grant or contract, an acceptable plan must be developed within 30 days. An investigator’s FCOI will be reviewed at least annually during the period of the award.

**RESOLUTION**

Examples of conditions or restrictions that may be imposed to manage, reduce or eliminate a potential conflict of interest include, but are not limited to:

1. Public disclosure of significant financial interests;
2. Monitoring of sponsored activities by independent reviewers;
3. Modification of the sponsored activity plan;
4. Disqualification from participation in all or a portion of the sponsored activity;
5. Divestiture of significant financial interests; or
6. Severance of relationships that create actual or potential conflicts of interest.

If the designated university official determines that imposing the above-referenced conditions or restrictions would either be ineffectve or inequitable, and that the potential negative impacts that may arise from a significant financial interest are outweighed by interests of scientific progress, technology transfer, or the public health and welfare, then the designated university official may recommend that, to the extent permitted by federal regulations, the sponsoring activity go forward without imposing such conditions or restrictions.

The approved resolution plan shall be documented in writing, detailing the conditions or restrictions imposed upon the investigator(s) in the conduct of the sponsored activity or in the relationship with the business enterprise or entity.

In accordance with specific agency regulations, the designated university official will notify the agency in writing of all identified conflicts of interest, including those which the University is unable to satisfactorily manage, reduce, or eliminate. Additional reports or information required by the agency involved will be provided.

**ENFORCEMENT**

The designated university official shall be responsible for determining and implementing sanctions on investigators who have violated this policy in terms of a conflict-of-interest resolution. The investigator shall be notified in writing of the recommended sanctions within 30 days. If the sanctions involve a recommendation of termination of employment, the University academic termination procedures will be invoked. The University must take action appropriate for the seriousness of the violation including, but not limited to, one or more of the following, subject to existing University policies for institutional disciplinary action:

1. Termination;
2. Removal from particular activity;
3. Special monitoring of future work;
4. Letter of reprimand; and/or
5. Probation for specified period with conditions specified.
The University shall follow federal regulations regarding the notification of the sponsoring agency in the event an investigator has failed to comply with this policy. The sponsor may take its own action as it deems appropriate, including the suspension of funding for the investigator until the matter is resolved.

Individuals may appeal the judgment and/or the sanction. A written statement of the grounds for the appeal must be submitted to the President within 30 days of written notification of the sanctions. Grounds for appeal include, but are not limited to, previously unconsidered material evidence, sanctions not commensurate with the finding, and failure to follow the prescribed process. Upon receipt of a written appeal, the President will evaluate the evidence and make a determination. The President will open an investigation if the previously unconsidered material evidence so warrants and may open an investigation if circumstances so dictate. The President’s decision will be conveyed to all involved in a timely fashion, but must be conveyed within 30 days. In the case of termination, the appropriate university policies on termination for cause shall be followed.

**SUB-RECIPIENT COMPLIANCE AND REPORTING FOR PHS-RELATED GRANTS AND CONTRACTS**

All proposed subrecipients under PHS-funded research of the University shall have a financial conflicts of interest policy that conforms to the requirements of the FCOI regulations. With respect to these subgrantees, subcontractors, and collaborators, the designated university official must require these entities to enter into a written agreement and make a certification to the University at the time of award that its financial conflicts of interest policy complies with the PHS FCOI regulations. The written agreement shall include all of the terms required under the PHS FCOI regulations.

The University, through the designated university official, will report to the PHS funding agency any FCOI which are identified by any subgrantee, subcontractor, or collaborator to the University in the manner required under the FCOI regulations, prior to the expenditure of funds and within sixty (60) days of any subsequently identified FCOI.

**CERTIFICATION**

The principal investigator must verify that he or she has disclosed all potential conflicts of interest and all other pertinent information by signing a certification statement. The statement is as follows:

"I certify that I have read and understand the Southwestern Oklahoma State University’s Policy on Conflict of Interest. I have made all financial disclosures, and I will comply with the Policy and any conditions or restrictions imposed by the University to manage, reduce, or eliminate actual or potential conflicts of interest."

The designated university official must also certify on behalf of the University that the institution has implemented and is enforcing a written policy on conflicts of interest. The statement for the designated university official is as follows:

“The designated university official certifies that all financial disclosures required by the conflict of interest policy were made; and that actual or potential conflicts of interests, if any, were, or prior to funding the award, satisfactorily managed, reduced or eliminated in accordance with the institution’s conflict of interest policy or disclosed to the agency involved.”

[Financial Conflict of Interest Disclosure Form](#)