

**CONFLICT OF INTEREST**

**Under**

**EXTERNALLY SPONSORED AGREEMENTS**

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## **I. OVERVIEW**

### **A. Purpose**

The purpose of this policy is to promote objectivity in externally sponsored projects by establishing standards to ensure there is no reasonable expectation that the design, conduct, or reporting will be biased by any conflicting financial interest of an investigator. To this end, Xavier University seeks to avoid any actual, apparent or hidden conflicts of interest between a Principal Investigator (hereinafter "PI") and Externally Sponsored Agreements (ESA). Government regulations require that funded institutions have policies and procedures in place to ensure that all faculty and staff working on a grant disclose any financial interests they have, or reasonably anticipate having, with a funded project. Such disclosure must be made (1) prior to proposal submission, or (2), if a conflict occurs later, at the time the conflict arise.

### **B. Scope and Statutory Authority**

This policy shall apply to all projects conducted under agreements that are externally funded, including the licensing of intellectual products. Xavier's policy is consistent with the following regulations and guidelines:

1. Public Health Service Regulations, "Objectivity in Research," 42 CFR § 50.603, *et seq*; 45 CFR § 94.3;
2. National Science Foundation Grant Policy Manual, § 510, *et seq*, "Investigator Financial Disclosure Policy";
3. OMB Circular A-110, "Subpart C. Post Award Requirements and Procurement Standards."

### **C. Policy/Duty of the Principal Investigator**

Every Principal Investigator that applies for and is awarded an externally funded project is charged with the duty to report any existing conflict of interest to Xavier's Associate Vice President for Research and Sponsored Programs. This obligation continues throughout the life of the grant. A Principal Investigator must update and amend his or her conflict of interest statement to reflect any conflicts of interest that arise after submission of a grant proposal to the funding agency. If a conflict of interest is disclosed, it is Xavier's policy to eliminate it, or to reduce and/or manage it, within the confines of acceptable standards.

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

- Institutional Financial Conflict Of Interest (FCOI) policies change in a manner that affects Investigator requirements
- An Investigator is new to an Institution
- An Institution finds an investigator noncompliant with Institution's FCOI policy or management plan.

## II. DEFINITIONS

A. A *Conflict of Interest* exists when the Designated Institutional Official reasonably determines that a significant financial interest could directly and significantly affect the design, conduct, or reporting of the externally sponsored program.

B. *Externally Sponsored Agreement* means a grant, contract, cooperative agreement or license between Xavier and any external agency.

C. *Institutional Official* means the Associate Vice President for Research and Sponsored Programs whose responsibility is to solicit and review financial disclosure statements from each Investigator who is planning to participate in any externally sponsored project.

D. *Investigator* means the Principal Investigator and any other person at Xavier University who is responsible for the design, conduct, and/or reporting of activities for the proposed or ongoing project.

E. *Significant Financial Interest* means anything of \$5,000 or more in monetary value for services and equity interests, including but not limited to, salary or other payments for services (e.g., consulting fees or honoraria); equity interests in non-publicly traded entities (stocks, bonds or interest therefrom); intellectual property rights (patents, copyrights and royalties therefrom); the occurrence of any reimbursed travel or sponsored travel related to Institutional responsibilities (including purpose of trip, sponsor/organizer, destination, and duration).

The term does **not** include:

1. Income from the applicant institution;
2. Any ownership interests in the institution, if the institution is an applicant under the SBIR<sup>1</sup> program;
3. Income from seminars, lecture, or teaching engagements sponsored by and service on advisory or review panels for 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;
4. Income from service on advisory committees or review panels for public or nonprofit entities;
5. An equity interest that when aggregated (and including the investigator's spouse and children) does not equal \$5,000 using fair market value prices, and an ownership interest of not more than five percent in any single entity;
6. Salary, royalties or other payments that when aggregated for the Investigator and the Investigator's spouse and children over the next twelve months, are not expected to exceed \$5,000;

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<sup>1</sup> *Small Business Innovation* means the extramural research program for small business that is established by the awarding components of the Public Health Service and certain other Federal agencies. See 45 CFR §94.3

7. Excludes interest 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;

8. Excludes travel that is reimbursed or sponsored by a federal, state, or local government agency, an Institution of higher education is 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 of disclosure of the monetary value.

### **III. RESPONSIBILITIES OF THE INSTITUTIONAL OFFICIAL**

The Institutional Official must:

- A. maintain an appropriate written, enforced policy of conflict of interest that complies with 45 CFR § 94.1, *et seq.* and 42 CFR § 50.601, *et seq.* and insures that the process will identify, manage, reduce or eliminate conflicting interests with respect to all externally sponsored programs;
- B. ensure that if funded projects are carried out through collaborators or subcontractors, such collaborators or subcontractors are in compliance with the reporting procedures of this policy;
- C. solicit and review conflict of interest statements submitted;
- D. require that a conflict of interest statement be submitted with the application at the time it is submitted to the external agency listing all significant financial interests of the PI that would reasonably appear to be affected by the project for which the funding is sought, and list all entities whose financial interests would reasonably appear to be affected by the project;
- E. require that all financial disclosures be updated during the period of the award, or on an annual basis, or as new reportable significant financial interests are obtained;
- F. provide guidelines consistent with this policy to identify conflicting interests and take such actions as are necessary to ensure that such conflicting interests will be managed, reduced, or eliminated;
- G. maintain records of all financial disclosures and all actions taken by the Associate Vice President for Research and Sponsored Programs with respect to any conflict of interest for a period of three years;
- H. establish adequate enforcement mechanisms and provide for sanctions where appropriate;
- I. certify in each proposal that there is in effect a written and enforced administrative process to identify and manage, reduce or eliminate conflicting interests with respect to all projects that are externally funded; and
- J. report to the funder, before any expenditure of funds, the existence of a conflict of interest and that it has been managed, reduced or eliminated, and, should any conflict of interest arise subsequently, it will be managed, reduced or eliminated within sixty days of that identification.

#### **IV. Management of Conflict of Interest**

The Associate Vice President for Research and Sponsored Programs must review all financial disclosures and determine whether a conflict of interest exists. If it appears that a conflict of interest does exist, the Associate Vice President for Research and Sponsored Programs will impose certain conditions or restrictions that might be used to manage conflicts of interests, including:

- A. public disclosure of significant financial interests;
- B. monitoring of the project by independent reviewers;
- C. modification of the project plan;
- D. disqualification from participation in all or a portion of the project;
- E. divestiture of significant financial interests, and/or;
- F. severance of relations that create actual or potential conflicts.

The following information should be included on an identified Financial Conflict of Interest (FCOI) reported by the Institution to the Federal Awarding Agency:

##### **Initial Report**

- Grant/Contract number
- Project Director/Principal Investigator (PD/PI) or Contact PD/PI
- Name of Investigator with FCOI
- Whether FCOI was managed, reduced, or eliminated
- Name of the entity with which the Investigator has a FCOI
- Nature of FCOI, e.g., equity, consulting fees, travel reimbursement, honoraria
- Value of the financial interest \$0-4,999; \$5K-9,999; \$10K-19,999; amounts between \$20K-\$100K by increments of \$20K; amounts above \$100K by increments of \$50K or statement that a value cannot be readily determined
- A description how the financial interest relates to federally funded research and the basis for the Institution's determination that the financial interest conflicts with such research
- Key elements of the Institution's management plan

##### **Annual Report**

In addition, an Annual Report is to be submitted to the Federal Awarding Agency containing:

- Status of the FCOI
- Changes to the management plan

#### **V. Procedure for Managing Alleged Conflict of Interest Violations**

The process used to manage alleged violations of this policy is described in Xavier's "Misconduct under Externally Sponsored Agreements" that is predicated in part on 42 U.S.C. § 681, *et seq.*