



## XAVIER UNIVERSITY

### Financial Conflict of Interest Policy-Federal Grant Proposals

**Effective Date:**

**Last Updated:** May 2013

**Responsible University Office:** Office of Grant Services

**Responsible Executive:** Associate Provost for Academic Affairs and Dean of the Graduate School

**Scope:** Faculty/Staff Submitting Federal Grant Proposals

#### A. REASON FOR POLICY

The federal government requires that the University establish and administer a financial disclosure policy for those Investigators (defined below) applying for federal funds and create a program for training Investigators in that policy. This is designed to ensure appropriate management of actual or potential conflicts of interest. This University policy is designed to fulfill the requirements of grantee institutions as put forth in the [National Institutes of Health's \(NIH\) guidelines](#) and is applicable to all Public Health Service (PHS) affiliated agencies. The policy is also designed to comply with the [National Science Foundation's \(NSF\) conflict of interest policies](#).

#### B. POLICY

**Disclosure of Significant Financial Interests.** All personnel responsible for the design, conduct or reporting of research under the terms of a federal grant or contract (each, an "Investigator") are required to disclose to the Institutional Official (Associate Provost for Academic Affairs and Dean of the Graduate School) all "Significant Financial Interests" of the Investigator and/or the Investigator's spouse, partner, and dependent children. See attached Financial Disclosure Form.

#### C. DEFINITIONS

**"Significant Financial Interest"** (SFI) means either (1) or (2) below:

(1) A financial interest consisting of one or more of the following interests of the Investigator (and those of the Investigator's spouse, partner, and dependent children) *that reasonably appears to be related to the Investigator's institutional responsibilities*:

(i) With regard to any publicly traded entity, an SFI exists if the value of any remuneration received from the entity in the twelve months preceding the completion of this questionnaire and the value of any equity interest in the entity as of the date of completion of this questionnaire, 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 interest includes any stock, stock option, or other ownership interest, as determined through reference to public prices or other reasonable measures of fair market value;

(ii) With regard to any non-publicly traded entity, an SFI exists if the value of any remuneration received from the entity in the twelve months preceding the completion of this questionnaire, when aggregated, exceeds \$5,000, or when the Investigator (or the Investigator's spouse, partner, or dependent children) owns any equity interest, regardless of dollar value. (iii) Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.

(2) Any reimbursed or sponsored travel (i.e., that which is paid on behalf of the Investigator and not reimbursed to the Investigator so that the exact monetary value may not be readily available), *related to their institutional responsibilities*, 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. The Investigator must disclose the purpose of the trip, the identity of the sponsor and/or organizer, the destination and its duration. Additional information, including the estimated cost of travel, may be requested by the Institutional Official and must be furnished upon request. **(This is only applicable to PHS affiliated agencies.)**

SFI does *not* include the following types of financial interests:

- a) salary, royalties, or other remuneration paid by Xavier to the Investigator if the Investigator is currently employed or otherwise appointed by the University, including intellectual property rights assigned to the University and agreements to share in royalties related to such rights;
- b) 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;
- c) income from seminars, lectures, or teaching engagements sponsored by a federal, state, or local government agency, an institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education; or
- d) income from service on advisory committees or review panels for a federal, state, or local government agency, an institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education.

**“Research”** is defined as any such activity (described at 42 CFR 50.603) for which research funding is available from a PHS Awarding Component (e.g., NIH) through a grant or

cooperative agreement, These include research grants, career development awards, center grants, individual fellowship awards, infrastructure awards, institutional training grants, program projects, or research resources awards.

**“Investigator”** is defined as the project director or principal investigator and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research funded by a federal agency, or proposed for such funding, which may include, for example, collaborators or consultants.

## **D. PROCEDURES**

### **1. Timing of Required Disclosures.**

a) Investigators must provide all required financial disclosures by completing the Financial Disclosure Form located on the Grant Services website at the time a proposal is submitted.

b) In addition, Investigators must update the Financial Disclosure Form:

- 1) Within thirty (30) days of discovering or acquiring (e.g., through purchase, marriage or inheritance) any new Significant Financial Interest; and
- 2) Annually within the period of the award, beginning with the anniversary date of the original disclosure.

**2. Review of Financial Disclosures.** The following process shall apply to financial disclosures submitted by Investigators.

a) Determination of Financial Conflicts of Interest (FCOI). The Institutional Official (Associate Provost for Academic Affairs and Dean of the Graduate School) shall review each disclosed SFI; determine whether such SFI relates to federally-funded research, and, if so related, determine whether a Financial Conflict of Interest (as defined below) exists; and determine what conditions or restrictions, if any, should be imposed by the University to manage, reduce, or eliminate such conflict of interest. The Institutional Official may, depending on the scope of the potential conflict, request that additional staff or faculty serve on an *ad hoc* review committee to assist in its timely review.

b) “Financial Conflict of Interest.” A “Financial Conflict of Interest” exists when the Institutional Official reasonably determines that a Significant Financial Interest could directly and significantly affect the design, conduct, or reporting of federally-funded research or educational activities.

c) Management of Financial Conflicts of Interest. If the Institutional Official determines that a Significant Financial Interest constitutes a Financial Conflict of Interest, the Institutional Official will convene a committee consisting of faculty, senior staff and/or outside experts (the “COI Committee”) whose make-up shall be determined in the discretion of the Institutional Official. The COI Committee will review the research, the Significant Financial Interest in question, and

the areas of conflict, and devise a plan for the management of the Financial Conflict of Interest. The Management Plan may include conditions or restrictions to manage, reduce, or eliminate Financial Conflicts of Interest, which may include (but are not limited to): a) monitoring of research by independent reviewers; b) modification of the research plan; c) disqualification from participation in the portion of the federally-funded research that would be affected by Significant Financial Interests; d) reduction or elimination of Significant Financial Interests; e) severance of relationships that create conflicts; or f) public disclosure of Financial Conflicts of Interest. The Investigator will be consulted as to the implementation of the Management Plan; the Investigator must agree to the plan before the research can proceed. If the COI Committee and the Investigator cannot agree upon a management plan, the relevant regulatory bodies and funding agencies will be notified.

d) Reporting of Financial Conflicts of Interest.

- 1) *Sponsoring agency.* Significant Financial Interests that are determined by the Institutional Official to be Financial Conflicts of Interest will be reported to the sponsoring agency in accordance with its requirements within 60 days of the original disclosure.
- 2) *Public request.* As required by sponsoring agency regulations, information on the nature of such Conflicts of Interest will be made available to members of the public by the Institutional Official in response to inquiries specifying the Investigator name and the research project in question within 5 business days of receipt of such requests.

**3. Investigator Non-Compliance.**

a) Disciplinary Action

In the event of an Investigator's failure to comply with this Policy, the Institutional Official in conjunction with the Investigator's supervisor 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. An 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 will notify the Investigator 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.

Upon completion of the retrospective review, if it involves a PHS agency, the Institutional Official will update any previously submitted report to the PHS or the prime PHS-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 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. The applicable PHS agency will consider the report and may take additional actions with respect to the funded activity such as imposition of special award conditions, suspension of funding or other enforcement actions.

**4. Records.** The University shall maintain records of all financial disclosures and of all actions taken to resolve Financial Conflicts of Interest for at least three years beyond the termination or completion of the grant to which they relate, or until the resolution of any federal action involving those records, whichever is longer.

## **5. Training**

**Investigators on NIH/PHS- proposals.** Each Investigator (including senior/key personnel) on projects funded by or proposed to NIH or other Public Health Service (PHS)-affiliated agencies must complete training on Conflict of Interest. Investigators must complete such training prior to participation in PHS-funded research and every four years thereafter as long as the project is active. This educational requirement is met by completing the “Conflicts of Interest” course located on the [CITI website](#). Instructions for registering and taking this course are found [here](#). Once Investigators have successfully completed the course they should print a completion certificate for their own records and send a copy to Grant Services. Grant Services will monitor compliance with this mandatory training requirement.

**Investigators on non-NIH/PHS proposals.** For Investigators sponsored by or seeking funding from NSF and/or other federal agencies, as well as any Investigators initiating research sponsored by a private, for-profit entity, the above training activities are optional but recommended.

**6. Disclosure Statement.** Copies of the University’s Financial Disclosure Form are available on the Grant Services website. This Financial Disclosure Form must be completed by all senior personnel who are submitting proposals to a federal funder. The certification page of a proposal cannot be signed until forms for all Investigators are submitted to the Institutional Official. By signing this form the applicant certifies that he/she has read the Financial Conflict of Interest Policy and that he/she either a) does not have potential Financial Conflicts of Interest (“*I hereby certify that I have read the Xavier Financial Conflict of Interest Policy- Federal Grant Proposals which is effective for all federal proposals submitted through the University. I certify to the best of my knowledge that neither I nor my spouse, partner, or dependents hold any significant financial interests that would reasonably appear to be related to my research, teaching and service responsibilities to Xavier University*”) or b) does have potential conflicts (“*I have the following relationships, affiliations, activities, or interests (financial or otherwise) which*

*constitute potential conflicts under the Xavier University Financial Conflict of Interest Policy-Federal Grant Proposals”). In either case, the applicant also declares that he/she will notify the Institutional Official of any change or discovery requiring modification of the above statement.*

**7. Subrecipients.** The University is responsible for ensuring all subrecipients’ compliance with the applicable federal regulations regarding Financial Conflicts of Interest. To this end, the University shall enter a written agreement with each subrecipient that shall specify whether this policy, or the applicable policy of the subrecipient’s institution, will apply to subrecipient Investigators. Said agreement will specify the timing for reporting of Financial Conflicts of Interest (a significant financial interest that could be directly and significantly affects the design, conduct, or reporting of PHS funded research) by subrecipients to Xavier University to enable the timely review and reporting of such FCOIs in compliance with funding agency requirements.

**E. EXHIBITS (if applicable)**

See attached Financial Disclosure Form.

**F. HISTORY**

This is an updated version of the Office of Grant Services-Investigator Financial Conflict of Interest Policy (1998).

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**Other applicable policies and/or resources:**

Financial Conflict of Interest-Non-Federal Grant Proposals  
2.16 Conflict of Interest



## Financial Disclosure Form-Federal Grant Proposals

Investigator Name:

Project Name:

Source of Funds:

Status:  Current  Pending

Role in Project:  PI  Co-PI  Senior/Key Personnel  Consultant  Unpaid Collaborator  Other Investigator

In making the following certification and representations, please remember that all the following must be *included* as significant financial interests:

- All financial interests pertaining to you personally;
- All pertaining to your spouse or partner;
- All pertaining to a dependent child.

The following types of financial interests are *excluded* and should not be reported on this form as significant financial interests:

- Salary, royalties, or other remuneration from Xavier University;
- Income from investment vehicles such as mutual funds or retirement accounts, as long as you do not directly control the investment decisions made in these vehicles;
- Income from seminars, lectures, or teaching engagements sponsored by, or service on advisory committees or review panels for, or travel sponsored or reimbursed by any or all of the following (U.S.-based entities only):
  - Federal, State or local government agencies
  - Institutions of higher education
  - Academic teaching hospitals
  - Medical centers
  - Research institutes affiliated with institutions of higher education.

Check one of the following statements:

*I hereby certify that I have read the Xavier University Financial Conflict of Interest Policy-Federal Grant Proposals which is effective for all federal proposals submitted through the University. I certify to the best of my knowledge that neither I nor my spouse, partner, or dependents hold any significant financial interests that would reasonably appear to be related to my research, teaching and service responsibilities to Xavier University.*

*I have the following relationships, affiliations, activities, or interests which constitute significant financial interests under the Xavier University Financial Conflict of Interest Policy-Federal Grant Proposals (see following pages):*

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Date

### Publicly Traded Entities

*Instructions: Copy as many times as needed for all publicly-traded entities. Do not include any company for which subtotal of all financial interests < \$5,000*

Company Name and Stock Market Abbreviation	Interests Pertaining to (check all that apply): <input type="checkbox"/> Self <input type="checkbox"/> Spouse / Partner <input type="checkbox"/> Dependent Child	Type of Interest  <input type="checkbox"/> Equity  <input type="checkbox"/> Compensation (total over last 12 calendar months)	Value of Interest		
			# Shares	Current Market Value	Total Value
			Total Value		
			Description of Relationship:		
Subtotal (Total Equity Value + Compensation over last 12 months)					

### Non-Publicly Traded Entities (Equity Interests)

*Instructions: List all non-publicly traded entities in which you, your spouse/partner and/or your dependent child hold an equity interest, regardless of dollar value. Add rows if needed.*

*Estimated \$ value and % ownership columns are optional, but the University reserves the right to request this information during the Conflict of Interest determination process if these are left blank.*

Entity Name	Interests Pertaining to (check all that apply): <input type="checkbox"/> Self <input type="checkbox"/> Spouse / Partner <input type="checkbox"/> Dependent Child	Entity Business Type	Estimated \$ Value	% Ownership
	<input type="checkbox"/> Self <input type="checkbox"/> Spouse / Partner <input type="checkbox"/> Dependent Child			
	<input type="checkbox"/> Self <input type="checkbox"/> Spouse / Partner <input type="checkbox"/> Dependent Child			

### Non-Publicly Traded Entities (Compensation)

*Instructions: List all non-publicly traded entities from which you, your spouse/partner and/or dependent child have received compensation of \$5,000 or more in the last 12 calendar months. All columns must be completed in full. Add rows if necessary.*

Entity Name	Interests Pertaining to (check all that apply): <input type="checkbox"/> Self <input type="checkbox"/> Spouse / Partner	Position or Relationship	Entity Business Type	Total Compensation in \$
	<input type="checkbox"/> Self <input type="checkbox"/> Spouse / Partner			



	<input type="checkbox"/> Dependent Child			
	<input type="checkbox"/> Self <input type="checkbox"/> Spouse / Partner <input type="checkbox"/> Dependent Child			

### Compensation for Intellectual Property Rights

*Instructions: This does not include any payment from Xavier University for intellectual property assigned to the University in conformance with the University's Intellectual Property policy. List all entities other than Xavier University from which you, your spouse/partner and/or your dependent child have received payment for intellectual property rights (e.g. royalties, licensing fees, etc.) in the last 12 calendar months. Add rows if necessary.*

Entity Name	Interests Pertaining to (check all that apply):	Description of Intellectual Property	Total Compensation in \$
	<input type="checkbox"/> Self <input type="checkbox"/> Spouse / Partner <input type="checkbox"/> Dependent Child		
	<input type="checkbox"/> Self <input type="checkbox"/> Spouse / Partner <input type="checkbox"/> Dependent Child		

### Sponsored or Reimbursed Travel (PHS Affiliated Agency Proposals ONLY)

*Instructions: List any instance of travel from the last 12 calendar months which was either sponsored or reimbursed by an entity other than Xavier University other than those types of entities excluded on page 1. Include any instance where reimbursement was made by Xavier University from a fund account sponsored by a non-excluded entity. Add rows if needed. Estimated cost column is optional, but the University reserves the right to request this information from you or the sponsor during the Conflict of Interest determination process if this space is left blank.*

Traveler (check all that apply)	Destination	Dates of Travel	Purpose of Travel	Sponsor Name or Reimbursement Source	Estimated costs in \$
<input type="checkbox"/> Self <input type="checkbox"/> Spouse / Partner <input type="checkbox"/> Dependent Child					
<input type="checkbox"/> Self <input type="checkbox"/> Spouse / Partner <input type="checkbox"/> Dependent Child					