



**Office of Research and Sponsored Programs**  
**Policy and Procedures on Financial Conflicts of Interest**  
**Related to Externally Sponsored Projects**

**INTRODUCTION**

Effective interaction between university employees, public agencies, and private sector businesses, including external sponsorship of research, instructional, and service activities, is essential to the mission of the institution. In accepting such sponsorship, the University has an obligation to protect a project from being compromised by conflicting financial interests of individuals responsible for it. It also has an obligation to protect the reputation and credibility of the University and of its employees, and to ensure public trust and confidence in its sponsored activities. This policy and related procedures regulate financial conflicts of interest in externally sponsored projects at the University.

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 and 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.

This policy does not supplant or obviate any provisions of the Louisiana Code of Governmental Ethics—Code of Ethical Standards for Public Servants (Louisiana Revised Statutes Title 42) or other general policies to which all University employees must comply. This policy is consistent with the U.S. Department of Health and Human Services (HHS) regulations: Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is Sought (42 C.F.R. Part 50, Subpart F) and Responsible Prospective Contractors (45 C.F.R. Part 94) as revised August 25, 2011. Where there are substantive differences between this policy and the requirements, the requirements shall take precedence.

Some requirements of this policy apply to any proposed or implemented externally sponsored project, regardless of sponsor, while other requirements are specific to proposals to and awards from the Public Health Service (PHS).

The requirements of this policy are separate from and in addition to those the requirements of the university's policy for Disclosure of Outside Employment (found at:

<http://apfd.louisiana.edu/resources/Disclosure-of-Outside-Employment-Spring-2011.pdf>)

and the Louisiana Code of Governmental Ethics (found at

[http://wwwprd.doa.louisiana.gov/laservices/publicpages/servicedetail.cfm?service\\_id=2571](http://wwwprd.doa.louisiana.gov/laservices/publicpages/servicedetail.cfm?service_id=2571)).

**DEFINITIONS**

**Family members** are defined as spouses, parents, parents of spouses, siblings, spouses of siblings, children, and spouses of children.

**Financial Interest** means anything of monetary value received or held by an Investigator or an Investigator's Family Member, 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. 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. **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;
- 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; or
- e) a controlling interest as defined herein.

**Significant Financial Interest (SFI)** 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.

**Controlling interest** means an ownership interest held by or on behalf of an individual or of immediate family members, individually or collectively, that exceeds 25% of the legal entity.

**Financial Conflict of Interest** means a Significant Financial Interest (or, where the Institutional Official requires disclosure of other Financial Interests that the Institution 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 Vice President for Research will serve as the Institutional Official.

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

***Investigator*** means any individual who is responsible for the design, conduct, or reporting of 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, subrecipient investigators, or consultants as appropriate.

***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.

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

***Subrecipient relationship*** means a relationship is established when federal funds flow down from or through an awardee institution to another individual or entity and the subrecipient will be conducting a substantive portion of the funded research project and is accountable to the awardee institution for programmatic outcomes and compliance matters. Accordingly, as a recipient of federal funds from an awardee Institution, the Financial Conflict of Interest policy applies to subrecipients (e.g., subcontractors or consortium members).

## **DISCLOSURE REQUIREMENTS**

All Investigators are required to disclose their outside financial interests to the Institution at the time of proposal submission, 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 and has tasked the Office of Research and Sponsored Programs with facilitating the procedural aspects of managing the requirements of this policy at the pre-award /proposal stage and Sponsored Programs Financial Administration and Compliance with facilitating the procedural aspects of managing the requirements of this policy in the post-award stage for awarded projects.

Regardless of the disclosure requirements, the Investigator, in his or her own best judgment, 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.

Financial interests reported as required by this policy might also require additional reporting to fulfill the requirement of the university's policy for Disclosure of Outside Employment and the Louisiana Code of Governmental Ethics.

### ***Disclosure at Time of Proposal/Application for External Funding***

At the time of submission of a proposal for external funding, all Investigators are responsible for certifying whether there is or is not Financial Interest or Significant Financial Interest related to the proposed project. The certification is accomplished on the *Internal Proposal Approval Form*. In addition the Principal Investigator is responsible for making a reasonable effort to determine whether any other project staff, including post-doctoral associates, graduate students, and undergraduate students, have any reportable Financial Interest or Significant Financial Interests. During this process, Investigators must also disclose reimbursed or sponsored travel related to their institutional responsibilities, as defined above in the definition of Financial Interest.

Financial interests related to externally sponsored projects are recorded on the *Financial Conflict of Interest Assurance and Disclosure Form*, which is submitted to the Office of Research and Sponsored Programs (ORSP) with the *Internal Proposal Approval Form* and complete proposal package. This form is used to report the existence of any Financial Interest or Significant Financial Interests related to any proposed externally funded project or which reasonably appear to be related to the Institutional Responsibilities of the Investigator. This reporting form must be submitted:

- a) for the individual with a reportable Financial Interest or Significant Financial Interest related to a proposal for funding when such financial interest currently exists or existed in the past three (3) years,
- b) for all investigators when submitting **any** proposal for **NSF** or **PHS** funding.

### ***Annual Disclosure for Externally Funded Projects***

Each Investigator participating in an externally funded project shall submit an updated disclosure at least annually during the period of the award. In addition to disclosing Financial Interests related to the awarded project or their institutional responsibilities, at the time of annual disclosure Investigators shall disclose their planned or anticipated reimbursed or sponsored travel in a prospective manner (e.g., over the next twelve months) and shall provide an update to the anticipated travel reported the previous year.

### ***Ad hoc Disclosures***

At any time during the proposal process or project administration when any new potential or actual financial interest arises, or when there are changes to existing potential or actual financial interests the investigators should submit a revised *Financial Conflict of Interest Assurance and Disclosure Form* within thirty days (30 days) of discovering or acquiring (e.g., through purchase, marriage, or inheritance) a new SFI.

## **REVIEW OF FORMS AND DEVELOPMENT OF MANAGEMENT PLANS**

ORSP will forward these forms to the Institutional Official for review. 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 exists when the Institutional Official or designee determines that a Financial Interest could directly and significantly affect the design, conduct, or reporting of PHS-supported research.

If the Institutional Official determines that there is a Financial Conflict of Interest, he or she must require and approve a written management plan before any related research goes forward. During this process, the Institutional Official may appoint an *ad hoc* committee to review the disclosure and to recommend a course of action. Before the Institutional Official reaches a decision, the individuals involved, including the person with the actual or potential conflict, shall be given the opportunity to meet with the Institutional Official (and with the *ad hoc* committee, if one is appointed) to discuss the actual or potential conflict and strategies for managing, reducing, or eliminating the conflict to be described in a Management Plan.

The affected Investigator is responsible for developing and submitting a proposed management plan, in consultation with the Institutional Official and *ad hoc* committee, if one is appointed. Key elements of a Management Plan shall include:

- a) Role and principal duties of the conflicted Investigator in the research project;
- b) Conditions of the management plan;
- c) How the management plan is designed to safeguard objectivity in the research project;
- d) Confirmation of the Investigator's agreement to the management plan;
- e) How the management plan will be monitored to ensure Investigator compliance; and
- f) Other information as needed.

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.

In support of this process, the Institutional Official shall seek input as appropriate from university, state or federal officials, legal counsel, or other advisors.

*If an Institution identifies an SFI that was not disclosed or reviewed in a timely manner, the designated official(s) shall within sixty (60) days review the SFI, determine if an FCOI exists and implement an interim management plan, if needed.*

## **INVESTIGATOR NON-COMPLIANCE**

### ***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.

A 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 individual of the right to appeal the decision.

### ***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, an ad hoc 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. The Institutional Official may appoint an ad hoc committee to assist with this process.

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.

In the case of PHS funded projects, 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.

#### **REPORTING TO SPONSORING AGENCY (INCLUDING PHS)**

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

#### **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 or to the prime PHS awardee.

#### **TRAINING REQUIREMENT FOR PHS FUNDED INVESTIGATORS**

Each Investigator must complete training on this policy prior to engaging in research funded by the Public Health Service (PHS), and at least every four years thereafter. 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.

#### **PUBLIC ACCESSIBILITY OF REPORTABLE SIGNIFICANT FINANCIAL INTERESTS RELATED TO PHS FUNDED RESERACH**

Prior to the expenditure of funds, the Institution will respond to any requestor as required by applicable law, 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 PHS-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 policy and shall include:

- a) Investigator's name;
- b) Investigator's title and role with respect to the research project;
- c) Name of the entity in which the SFI is held;
- d) Nature of the SFI; and
- e) Approximate dollar value of the SFI (dollar ranges are permissible: \$0-\$4,999; \$5,000-\$9,999; \$10,000-\$19,999; amounts between \$20,000-\$100,000 by increments of \$20,000; amounts above \$100,000 by increments of \$50,000), or a statement that the interest is one whose value cannot be readily determined through references to public prices or other reasonable measures of fair market value.