



POLICY STATEMENT 98

FINANCIAL CONFLICTS OF INTEREST IN RESEARCH

POLICY DIGEST

Monitoring Unit: Office of Research & Economic Development

Initially Issued: January 7, 2013

Last Revised: June 21, 2019

I. PURPOSE

This Policy promotes objectivity in all externally funded research by establishing standards to identify and address potential, actual, and apparent Financial Conflict of Interests. When an individual has an outside economic interest that can affect the conduct of their LSU institutional duties, a Financial Conflict of Interest exists that may threaten the objectivity and integrity of research. While this is not always problematic, certain consideration must be given to determine when these outside economic interests may bias, or have the appearance of biasing the design, conduct, or reporting of externally funded research. Objectivity of researchers is essential in scientific research for the maintenance of public trust, and the health and safety of those relying on the integrity of the research.

II. GENERAL POLICY

This Policy governs the disclosure of individual Significant Financial Interests and the management and reporting of an individual Financial Conflict of Interest in research performed at LSU and implements the federal regulations promulgated by the Public Health Service (PHS) of the US Department of Health and Human Services (DHHS), as well as those adopted by the National Science Foundation (NSF). (42 CFR Part 50; 45 CFR Part 94; National Science Foundation Proposal and Awards Policies and Procedures Guide.)

This Policy applies to all individuals engaged in externally funded research who, regardless of title or position, are responsible for the design, conduct, or reporting of the funded research, including but not limited to, principal investigators, co-investigators, and project directors. If a specific federal law, regulation, policy, or contract of a sponsor or prime awardee provides different requirements than this Policy, the more stringent requirement applies.

III. DEFINITIONS

Conflict of Interest Committee (COI Committee) means the Institution's committee or individual that advises the Institutional Official on Financial Conflict of Interest matters.

Entity means any domestic or foreign, public or private, organization (excluding a Federal agency) from which an Investigator (and spouse and dependent children) receives remuneration or in which any person has an ownership or equity interest.

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

Financial Conflict of Interest means a Significant Financial Interest that the Institution reasonably determines could directly and significantly affect the design, conduct or reporting of externally funded research.

Institutional Official means the individual within the Institution who 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 the Vice President for Research & Economic Development (VP ORED) or their designee.

Investigator means the project director, principal Investigator, co-investigator, and any other individual, regardless of title or position, who is responsible for the design, conduct, or reporting of externally funded research, or proposals for such funding.

Investigator's Institutional Responsibilities means the Investigator's responsibilities associated with their Institutional appointment or position, such as research, research consultation, teaching, clinical activities, administration, internal professional committee service such as a committee membership in Institutional Review Board (IRB) or Institutional Animal Care and Use Committee (IACUC), and external professional committee service.

Significant Financial Interest means a financial interest of the Investigator and their Family 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;
- 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;
- 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.

Significant Financial Interest also includes 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; provided however, that this disclosure requirement does not apply to travel that is 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 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, teaching engagements, advisory committees or review panels sponsored by or from 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.

Research: a systematic investigation, study, or experiment designed to contribute to generalizable knowledge. The term encompasses basic and applied research, product development, and educational activities.

IV. PRODECURES

A. When to Disclose a Financial Conflict of Interest

1. Time of Application

Prior to submitting an application, investigators must have submitted a Significant Financial Interests Disclosure. Investigators shall further certify that the proposed project conforms to this policy.

2. Annual Disclosure

Investigators with active external funding shall submit an updated Significant Financial Interests Disclosure on an annual basis.

3. Ad Hoc Disclosure

Within 30 days of acquiring or discovering a new Significant Financial Interest, the investigator shall submit an updated Significant Financial Interests Disclosure.

4. Additional Sponsor Requirements

For all externally funded sponsored projects, disclosure shall be in accordance with sponsor requirements if they are more restrictive than this policy.

B. Review, Determination and Management of Financial Conflict of Interest

1. Review and Determination

If the disclosure form reveals a Significant Financial Interest, it will be reviewed promptly by the Institutional Official for a determination of whether it constitutes a Financial Conflict of Interest. The Institutional Official may appoint a COI Committee for consultation and guidance in specific or complex cases, or the application of the policy to a particular situation.

A Financial Conflict of Interest will exist when the Institutional Official determines that a Significant Financial Interest could directly and significantly affect the design, conduct, or reporting of externally funded research.

2. Management

If the Institutional Official determines that there is a Financial Conflict of Interest, they must require and approve a written management plan before any related research goes forward or any funds can be expended. The affected Investigator or the COI Committee, as appropriate, is responsible for developing and submitting a proposed management plan for approval by the Institutional Official.

A management plan may impose any condition and prescribe any action necessary to manage a Financial Conflict of Interest, including an action reducing or eliminating the Financial Conflict of Interest, to ensure that the design, conduct, or reporting of the research is free from bias or the appearance of bias. Examples of conditions or actions that may be prescribed include, but are in no way limited to:

- a. public disclosure of the conflict of interest in presentations and publications;
- b. for human subjects research, direct disclosure of the conflict of interest to research participants;
- c. appointment of an independent monitor with authority to take measures to protect the design, conduct, and reporting of research against bias, or the appearance of bias, resulting from the conflict of interest;
- d. modification of the research plan;
- e. change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the research;
- f. divestiture or reduction of the financial interest; or
- g. severance of relationships that create an actual or potential Financial Conflict of Interest.

The management plan must be in the form of a written agreement and must provide that the Investigator acknowledges receipt of the approved plan and understands the requirements of this Policy and the required actions and other terms of the plan.

3. Reporting

Should any Financial Conflict of Interests or non-compliance require reporting to funding agencies which require such disclosure and reporting, the Office of Sponsored Programs (OSP), in consultation with the Institutional Official or the COI Committee, will report as required.

4. 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.

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 or the COI Committee, as applicable, 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, the Institutional Official or the COI Committee, if designated by the Institutional Official, will complete a retrospective review of the Investigator's activities and the funded research projects to determine whether the funded research conducted during the period of non-compliance was biased in the design, conduct or reporting of such research.

The OSP, in consultation with the Institutional Official or the COI Committee, will report to the funding agency any Financial Conflict of Interests determined as a result of the retrospective review in accordance with regulations of the funding agency. If bias is found through retrospective review, OSP, in consultation with the Institutional Official or the COI Committee, will notify the funding agency promptly and submit a mitigation report in accordance with regulations of the funding agency.

5. Training Required in Conflicts of Interest

Each Investigator must complete training and provide proof of completion of training on this Policy prior to engaging in research as required by the funding agency. For projects funded by PHS, training is required and must be renewed at least every four years thereafter. Investigators 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, when an investigator is new to the institution, or if it is determined that the Investigator has not complied with this Policy or with a management plan related to their activities. The Office of Sponsored Programs (OSP), in consultation with the Institutional Official, is responsible for ensuring that each Investigator, as defined herein, completes training as required under this Policy.

6. 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 funding agency, the date of final resolution of any

investigation, audit, or similar action involving the records, or as specifically required by the funding agency, whichever is later.

7. 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 when required by law, mandated by funding agency, or determined to carry out the purpose and administration of this policy. 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.

8. Public Accessibility

a. Public Accessibility Required by PHS

Institution shall make this Policy available via a publicly accessible website. Institution will respond to any requestor within five business days of the request concerning any Significant Financial Interests held by PHS Investigators that meets the following criteria:

- i. The Significant Financial Interest was disclosed and is still held by the Investigator;
- ii. A determination has been made that the Significant Financial Interest is related to the PHS-funded research; and
- iii. A determination has been made that the Significant Financial Interest is a Financial Conflict of Interest.
- iv. The information to be made publicly available shall be consistent with the requirements of the PHS policy.

b. Public Accessibility Required by Other Agencies

Should any other funding agency require public accessibility of Financial Conflict of Interests, the Institution shall provide such public access as required.

9. Subrecipients

If externally funded research involves a subrecipient, the Institution will take reasonable steps to ensure that any subrecipient investigator complies with the funding agency's Financial Conflict of Interest policy by:

- a. Establishing in writing with the subrecipient whether this Policy or the subrecipient's Financial Conflict of Interest policy will apply to the subrecipient's Investigators.
- b. Requiring Financial Conflict of Interest reports regarding all identified Financial Conflict of Interests of all subrecipient Investigators be provided to Institution for reporting to funding agency as applicable.

V. SOURCES

Public Health Service (PHS) of the US Department of Health and Human Services (HHS), (42 CFR Part 50; 45 CFR Part 94)

<https://www.ecfr.gov/cgi-bin/textidx?c=ecfr&SID=992817854207767214895b1fa023755d&rgn=div5&view=text&node=42:1.0.1.4.23&idno=42#sp42.1.50.f>

National Science Foundation Proposal and Awards Policy and Procedures Guide.
https://www.nsf.gov/publications/pub_summ.jsp?ods_key=nsf19001

Federal Demonstration Partnership (FDP) Model Financial Conflict of Interest Policy
http://thefdp.org/default/assets/File/Documents/fdp_model_coi_policy.docx