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LSU FINANCIAL CONFLICTS OF INTEREST IN RESEARCH

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 by implementing 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 Award and Administration Guide, Chapter IV. A.)

Scope:

This Policy applies to all individuals engaged in Public Health Service (PHS) and National Science Foundation (NSF) 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. In addition, this Policy shall apply to other funding agencies who require LSU Investigators to disclose any Financial Conflict of Interests, or when LSU system expands the application of this Policy. 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.

Note: This Policy does not replace or supersede general institutional or system policies, such as policies on standards of conduct, as well as other policies governing disclosure of activities and financial interests relating to outside employment and interests (PM 11 and PM 67).

Purpose:

This Policy promotes objectivity in PHS, NSF and other applicable agencies 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 PHS, NSF and other applicable agencies 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.

1. 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 PHS, NSF and other applicable agencies 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 Chancellor for Research and Economic Development (VC ORED) or his or her designee.

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 or consultants as appropriate.

Investigator's Institutional Responsibilities means the Investigator's responsibilities associated with his or her 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 .

NSF Significant Financial Interest means anything of monetary value, including, but not limited to, salary or other payments for services (e.g., consulting fees or honoraria); equity interest (e.g., stocks, stock options or other ownership interests); and intellectual property rights (e.g., patents, copyrights and royalties from such rights).

NSF Significant Financial Interest does NOT include:

- a) salary, royalties or other remuneration from the applicant institution;
- b) any ownership interests in the institution, if the institution is an applicant under the Small Business Innovation Research Program or Small Business Technology Transfer Program;
- c) income from seminars, lectures, or teaching engagements sponsored by public or non-profit entities;

- d) income from service on advisory committees or review panels for public or nonprofit entities;
- e) an equity interest that, when aggregated for the investigator and the investigator's spouse and dependent children, meets both of the following tests: (i) does not exceed \$10,000 in value as determined through reference to public prices or other reasonable measures of fair market value; and (ii) does not represent more than a 5% ownership interest in any single entity; or
- f) salary, royalties or other payments that, when aggregated for the investigator and the investigator's spouse and dependent children, are not expected to exceed \$10,000 during the twelve-month period.

PHS Significant Financial Interest means a financial interest that reasonably appears to be related to the Investigator's Institutional Responsibilities, and:

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 per PHS Guidelines;

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;

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

is income related to intellectual property rights and interests not reimbursed through the Institution.

PHS 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.

PHS Significant Financial Interest does NOT include:

salary, royalties, or other remuneration from the Institution;

income from the authorship of academic or scholarly works;

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; or 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.

PHS Senior/Key Personnel means the PD/PI and any other person identified as senior/key personnel by the Institution in the grant application, progress report, or any other report submitted to the PHS by the Institution under the regulation.

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).

2. When to Disclose a Financial Conflict of Interest

2.1. Time of Application

For PHS and NSF funding, at time of application, investigators shall indicate on the Sponsored Programs System (SPS) Cover Sheet whether there are any Significant Financial Interests. If investigator checks the box indicating the existence of a Significant Financial Interests, the investigator shall submit a Significant Financial Interests Disclosure Form to the Office of Sponsored Programs (OSP). Further, investigators shall certify on the SPS Routing Screen that the project conforms with this policy, and the absence of a check mark on the SPS Cover Sheet signifies there are no Significant Financial Interests.

2.2. Prior to Award Acceptance

For PHS funded research, prior to award acceptance, and on an annual basis (two months prior to the annual progress report due date) the investigators shall complete and submit to the Office of Sponsored Programs (OSP) a Significant Financial Interests Disclosure Form.

2.3. During the Award Period

For PHS and NSF, within 30 days of acquiring or discovering a new Significant Financial Interest, the investigator shall complete and submit to OSP a Significant Financial Interests Disclosure Form.

2.4. Disclosure for Funding Agencies Other than PHS and NSF

For all other sponsored projects that require disclosure of Significant Financial Interests, disclosure shall be in accordance with sponsor requirements.

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

3.1. 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 research funded by PHS, NSF, or other applicable agencies.

3.2. Management

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 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:

- public disclosure of the conflict of interest in presentations and publications;
- for human subjects research, direct disclosure of the conflict of interest to research participants;
- 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;
- modification of the research plan;
- change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the research;
- divestiture or reduction of the financial interest; or
- 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.

4. Reporting

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

In general, PHS regulations require a Financial Conflict of Interests Report include specified information sufficient to enable the awarding component to understand the nature and extent of the financial conflict and to assess the appropriateness of the management plan.

5. Non-Compliance

5.1. 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.

5.2. Retrospective Review Required by PHS

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

6. Training Required by PHS

Each Investigator must complete training and provide proof of completion of training on this Policy prior to engaging in research funded by 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, 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.

Financial Conflict of Interests Training will be attained via the Collaborative Institutional Training Initiative's (CITI) Financial Conflict of Interest Module. Upon successful completion, Investigator, as defined herein, shall provide a completion certificate to the Office of Sponsored Programs.

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.

7. 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 or, where applicable, from other dates specified in 45 C.F.R. 74.53(b) and 92.42 (b) for different situations.

8. 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 to an agency funding research of the faculty member, to a requestor of information concerning Financial Conflict of Interests related to PHS, NSF or other applicable agency funding, if requested or required. 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.

9. Public Accessibility

9.1. Public Accessibility Required by PHS

Institution shall make this Policy available via a publically accessible website. Prior to the expenditure of funds, Institution will publish on a publicly-accessible website or respond to any requestor within five business days of the request, information concerning any Significant Financial Interests held by PHS senior/key personnel that meets the following criteria:

The Significant Financial Interest was disclosed and is still held by the senior/key personnel;

A determination has been made that the Significant Financial Interest is related to the PHS-funded research; and

A determination has been made that the Significant Financial Interest is a Financial Conflict of Interest.

The information to be made publically available shall be consistent with the requirements of the PHS policy.

Section 9.2. 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.

10. Subrecipients

10.1 PHS and NSF Funded Research

If PHS or NSF funded research involves a subrecipient, the Institution will take reasonable steps to ensure that any subrecipient investigator complies with the PHS/NSF Financial Conflict of Interest policy by:

Establishing in writing with the subrecipient whether this Policy or the subrecipient's Financial Conflict Interest policy will apply to the subrecipient's Investigators.

If the subrecipient's Investigators must comply with the subrecipient's Financial Conflict of Interest policy, the subrecipient shall certify that its policy is in compliance with PHS/NSF requirements. In the absence of this certification, the agreement will state that subrecipient Investigators are subject to this Policy for disclosing Significant Financial Interests that are directly related to the subrecipient's participation in such PHS/NSF funded research.

Additionally, if the subrecipient's Investigators must comply with the subrecipient's Financial Conflict of Interest policy, the written agreement will specify a deadline for the subrecipient to report all identified Financial Conflict of Interests to the Institution so that the Institution can provide timely Financial Conflict of Interests reports, as necessary, to PHS/NSF.

Alternatively, if the subrecipient's Investigators must comply with this Policy, the written agreement will specify a deadline for the subrecipient to submit all Investigators' disclosures of Significant Financial Interests to the Institution so that the Institution can review, manage, and report identified Financial Conflict of Interests to PHS/NSF in a timely manner.

II. Providing Financial Conflict of Interest reports to PHS/NSF regarding all identified Financial Conflict of Interests of all subrecipient Investigators consistent with this Policy.

10.2 Other Agencies Funded Research

If other agencies funded research requires the disclosure of Financial Conflict of Interests of a subrecipient, the Institution shall ensure subrecipient's compliance in accordance with such agencies' requirements.

11. Sources

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

National Science Foundation Award and Administration Guide, Chapter IV. A.

Federal Demonstration Partnership (FDP) Model Financial Conflict of Interest Policy

