

**UNIVERSITY OF LOUISIANA AT MONROE
POLICIES AND PROCEDURES MEMORANDUM**

<i>Title:</i>	FINANCIAL CONFLICT OF INTEREST FOR NSF-, NIH-, AND PHS-SPONSORED PROJECTS
<i>Effective Date:</i>	8/24/12
<i>Update Responsibility:</i>	Academic Affairs
<i>Revision Date:</i>	None
<i>Cancellation Date:</i>	None

1. PURPOSE/PREAMBLE

The purpose of this interim policy for Financial Conflict of Interest for NSF-, NIH-, and PHS-sponsored projects is to ensure that all individuals affiliated with the University of Louisiana at Monroe (ULM), participating in research activities funded by the National Science Foundation (NSF) or Public Health Service (PHS includes NIH, the Centers for Disease Control and Prevention, and other agencies), are familiar and comply with the federal regulations on Objectivity in Research, and that ULM meets all requirements to ensure its continued eligibility to receive grants and contracts from these agencies. Failure to comply with this policy can jeopardize continued or future funding from these agencies.

ULM shall adhere to the standards and procedures set forth in this policy in monitoring significant financial interests and managing disclosed financial conflicts of interest for investigators who propose or receive funding from the NIH, the NSF or the PHS, in order to comply with federal regulations.

ULM employees can be subject to the disciplinary process of the University if they fail to fully and truthfully disclose financial conflict of interest situations or fail to comply with any stipulated plan for managing the disclosed conflict.

2. BACKGROUND

The NIH, NSF and PHS have issued regulations on Financial Conflict of Interest (FCOI) as related to research funded by these agencies. ULM recognizes that scholars and other staff engage in many relationships with outside entities, some of which might create a financial conflict of interest, or the appearance of a conflict of interest. These conflicts are increasingly common and sometimes unavoidable in a modern research setting. For example, an investigator, through federal grants, may develop a methodology, which could be commercialized in the private sector.

If the investigator has a financial interest in a small business in order to bring such a methodology to market, the relationship between the individual and the small business could be the source of potential conflicts of interest.

ULM, therefore, recognizes its obligation to ensure that research and other scholarly activities are carried out under the highest standards of integrity and ethical conduct. This policy serves to protect the interests of the scholarly community of the University by advancing an important goal: defense of the integrity and objectivity of the research carried out by our researchers.

This policy describes a disclosure process separate from annual certifications submitted to other University units. Investigators who are required to make a disclosure under this policy may or may not also be required to disclose financial interests on other required forms and procedures. Individuals may consult with their unit supervisor or the Office of Sponsored Programs and Research (OSPR) for more information.

3. APPLICABILITY

This policy applies to all University employees and affiliated staff, regardless of title, who are responsible for the design, conduct or reporting of research activities funded by NIH, NSF, or PHS through an award to the University, or through a subaward from another institution that has been funded directly by NIH, NSF, or PHS.

4. DEFINITIONS

- *Affiliated staff* means individuals other than employees who perform duties for the University or who operate on University property, including but not limited to contractors, volunteers, interns, visiting researchers and students, and research associates and collaborators.
- *Investigator* is the project director (PD), principal investigator (PI) or co-principal investigator (co-PI), or other person, regardless of title, who is responsible for the design, conduct, or reporting of research funded by the NIH, NSF, or PHS, or in proposals for such funding.
- For the purposes of this policy, the *financial interests of the investigator* include the financial interests of his or her spouse and dependent children, according to NIH, NSF, and PHS requirements.
- *Research* means a systematic investigation designed to develop or contribute to generalizable knowledge, including biomedical, behavioral and social-sciences or other scholarly activity. The term encompasses basic and applied research and product development.
- *Significant Financial Interest (SFI)* is defined in Code of Federal Regulations at 42 CFR part 50.603. The 2011 revised regulations defines SFI as follows:
 1. A financial interest consisting of one or more of the following interests of the investigator (and those of the investigator's spouse 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 12 months preceding the disclosure and the value of any equity interest in the entity as of the date of disclosure, when aggregated, exceeds \$5,000. 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 12 months preceding the disclosure, when aggregated, exceeds \$5,000, or when the investigator (or the investigator's spouse or dependent children) holds any equity interest (e.g., stock, stock option, or other ownership interest); or
 - iii. Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.
 2. The occurrence of 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; however, this disclosure requirement does not apply to travel that is reimbursed or sponsored by a government agency (federal, state, or local), an institution of higher education, or its affiliated entities, such as an academic teaching hospital, medical center, or research institute.

3. An SFI does not include the following:

- i. Salary, royalties, or other remuneration paid by the University, including intellectual property rights and agreements to share in royalties related to such rights;
- ii. 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;
- iii. Income from seminars, lectures, or teaching engagements sponsored by a government agency or institution of higher education; or
- iv. Income from service on advisory committees or review panels for a government agency or institution of higher education.

- Financial Conflict of Interest (FCOI) is said to exist if an SFI could directly and significantly affect the design, conduct, or reporting of NIH, NSF-, or PHS-funded research.
- Managing a financial conflict of interest means taking action to address an FCOI, which can include reducing or eliminating the FCOI to ensure, to the extent possible, that the design, conduct, and reporting of research will be free from bias.

Examples of conditions or restrictions that might be imposed to manage an FCOI include, but are not limited to: public disclosure of FCOI (e.g., when presenting or publishing the research); disclosure of FCOI directly to human subject participants; appointment of an independent monitor capable of taking measures to protect the design, conduct, and reporting of the research against bias resulting from the FCOI; modification of the research plan; change of personnel or personnel responsibilities; reduction or elimination of the financial interest (e.g., sale of an equity interest); and severance of relationships that create financial conflicts.

Any actual financial conflicts of interest will be managed by consultation with an *ad hoc* FCOI committee and the development of a management plan for the conflict. The *ad hoc* committee will consist of at least three persons, and may include a researcher from the investigator's unit, a representative from OSPR, a representative of Graduate School, or representatives of other areas as may be appropriate to ensure balanced representation of disciplines and interests. FCOI management plans will include a description of how the SFI is related to NIH-, NSF-, or PHS-funded research and will specify the actions that have been and will be taken to manage such FCOI.

5. RESPONSIBILITIES

- Vice President for Academic Affairs, Vice President for Student Affairs, Chief Business Officer, and the Executive Vice President are responsible for implementing FCOI policies and ensuring the availability of necessary FCOI training resources for University employees. If a potential financial conflict is disclosed, the appropriate Vice President will convene an *ad hoc* financial conflict of interest committee to review the matter and to develop a management plan for the conflict.
- Through deans and other equivalent non-academic personnel, Unit Supervisors are responsible for ensuring that the appropriate individuals within their unit submit disclosures of significant financial interests and complete periodic training in FCOI, if they are investigators funded by NIH, NSF, or PHS. If a potential financial conflict is disclosed, the unit director or designee will assist the appropriate senior level personnel in the convening of an *ad hoc* committee to review the matter and to develop a management plan for the conflict.
- Investigators who conduct activities governed by this policy are responsible for ensuring that they make disclosures at the following times:

- a. When they submit a proposal for funding;
- b. When they receive an award;
- c. Annually during the term of the award; and
- d. Within 30 days of discovering or acquiring a new SFI.

Investigators will complete training prior to engaging in research related to any NIH-, NSF-, or PHS-funded grant and at least every four years thereafter. Investigators who bring an NIH, NSF, or PHS grant with them to the University as new employees will complete training within 30 days upon being hired. Investigators will complete new training whenever this policy or related procedures are revised. If a conflict is found to exist, investigators are responsible for complying with the terms of an institutional FCOI management plan. Investigators will complete additional training whenever the investigator is found not to be in compliance with either this policy or a management plan created to manage a disclosed FCOI.

- Office of Sponsored Programs and Research will
 - a. provide training in financial conflict of interest to university community and will inform all investigators of their responsibility to complete training on this policy, their obligation to disclose SFIs, and of the content of NIH, NSF, and PHS regulations regarding financial conflict of interest.
 - b. maintain records of the disclosure process for investigators applying to, and all university investigators receiving awards from, NIH, NSF, or PHS.
 - c. ensure that the Graduate School Director reviews disclosures from all university investigators within 60 days and will determine whether any SFI is related to NIH-, NSF-, or PHS-funded research. In addition, in the event of a potential conflict of interest, OSPR will confer with the appropriate senior personnel to convene an *ad hoc* committee to review the case and implement a management plan that shall specify the actions that have been and will be taken to manage such FCOI.
 - d. prior to the expenditure of any funds under an NIH-, NSF-, or PHS-funded research project, provide to the appropriate funding agency an FCOI report regarding any investigator's SFI found by the University to be a conflict of interest and ensure that the University has implemented a management plan in accordance with NIH, NSF, or PHS regulations. OSPR will provide to the appropriate funding agency, within 60 days of the disclosure, a revised FCOI report if any new SFIs are identified subsequent to the initial report and ensure that the University has implemented a management plan.
 - e. maintain a publicly accessible website to report on the existence and management of any financial conflicts of interest, in accordance with 42 CFR Part 50 and 45 CFR Part 94. The information will be updated as described by NIH, NSF, and PHS regulations, at least annually, or within 60 days of identification of information that was not previously disclosed.

6. PROCEDURES

- A. At the time the proposal for external funding is routed for approval, the principal investigators are responsible for:
 1. including a completed *University of Louisiana at Monroe Screening Form for Identifying Conflicts of Significant Financial Interests* (Screening Form) for certifying that there is no investigator conflict of interest or for disclosing the existence of possible conflicts of interest related to the proposed project, and
 2. securing a completed *Screening Form* for all other investigators and key personnel listed in the proposal.

The screening form includes the following attestation:

"I certify that I have no potential financial conflict of interest that would impair my ability to participate on the proposed project, or if so, that I will advise OSPR immediately of any potential conflict. Conflict of interest includes aggregated equity interest/salary/royalties exceeding \$5000 in value, and/or more than a 5% ownership interest in any single source for yourself or immediate family members. The Institution will be responsible for notifying the sponsor within 60 days of any conflict of interest found and the method of correction taken."

Screening form is saved in the proposal file and should the award be made, is moved to and stored as a permanent part of the award file.

If an investigator identifies SFI at the time of proposal submission, the review and management process described below will be triggered.

- B. At the time of award weekly reports of new awards are reviewed to identify new NSF and PHS awards to university investigators. For each new covered award, a letter is prepared requesting the completion of a new disclosure form, specific to the new award, and addressed to the PI and any co-PIs. For an NSF subaward received by University from a prime awardee organization, the person responsible for that project is referred to as "co-PI." The new disclosure includes the definition of Significant Financial Interest (SFI), as defined at 42 CFR 50.603 (PHS policy). A response is requested within two weeks. If no response is received, the request is repeated, with a copy to the fund manager. Follow-up is by phone. Failure to complete the disclosure within 30 days will result in loss of spending authority on the grant.
- C. Notification of conflict - If OSPR's or Graduate School's opinion is that an SFI is related to NIH-, NSF-, or PHS-supported research, OSPR will contact the appropriate senior administrator and the Investigator to notify them that the case is being moved to the next level. This notification will take place within 30 days of the disclosure.
- D. Calling of ad hoc FCOI committee - In consultation with the appropriate senior administrator, OSPR will assist in the convening of an *ad hoc* committee to review the case.
- E. Management of FCOI - Managing a financial conflict of interest means taking action to address an FCOI, which can include reducing or eliminating the FCOI to ensure, to the extent possible, that the design, conduct, and reporting of research will be free from bias.

Examples of conditions or restrictions that might be imposed to manage an FCOI include, but are not limited to: public disclosure of FCOI (e.g., when presenting or publishing the research); disclosure of FCOI directly to human subject participants; appointment of an independent monitor capable of taking measures to protect the design, conduct, and reporting of the research against bias resulting from the FCOI; modification of the research plan; change of personnel or personnel responsibilities; reduction or elimination of the financial interest (e.g., sale of an equity interest); and severance of relationships that create financial conflicts.

Following the procedures outlined above in 6.C-D investigators will be given 7 days to respond to proposed management plan. If there is no response, the plan will be considered to be in effect. The University may monitor the investigator's compliance with the management plan. Investigators who fail to comply with an approved management plan are subject to the disciplinary process of the University.

- F. Retrospective reviews - If OSPR or other University party discovers an SFI that was not identified in the disclosure process, OSPR will initiate a retrospective review with the appropriate senior administrator. The initial review, conducted by the Graduate School Director and the appropriate senior administrator, will be to determine if the SFI is a FCOI and if the FCOI has led

to the collection and/or the reporting of biased data. The review will be conducted within 30 days of the discovery. If an FCOI is suspected, an *ad hoc* committee will be convened, as above, to make a determination of FCOI, and to investigate whether or not there was bias involved in the collection and/or reporting of data. The investigation will include interviews with relevant personnel, reviews of lab notebooks or raw data, if applicable, and any publications resulting from the research.

The *ad hoc* committee will proceed with development of a management plan for the new FCOI, which will include a mitigation plan to address the impact of the bias on the research.

7. REPORTING REQUIREMENTS/COMPLIANCE

A. Reporting of FCOI to sponsor

OSPR will report any disclosed FCOIs to the appropriate funding agency as required by regulations, namely, prior to the expenditure of funds, within 60 days of the identification of an investigator who is newly participating in the project, or within 60 days for new, or newly identified FCOIs for existing investigators. OSPR will also report at least annually, at the same time as when ULM is required to submit the annual progress report, multi-year progress report, if applicable, or at the time of no-costs extension, to provide the status of the FCOI and any changes to the management plan, if applicable, until the completion of the project. OSPR will report to the appropriate funding agency following a retrospective review to update a previously submitted report, as appropriate.

The elements that will be included in any FCOI report are:

- a. project number,
- b. project title,
- c. PI name,
- d. the name of the investigator with the FCOI, title, role on the project,
- e. the name of the entity in which the SFI is held,
- f. the nature of the SFI (equity, consulting fee, travel reimbursement, honorarium),
- g. the approximate dollar value of the SFI or a statement that the SFI is one whose value cannot be readily determined through reference to public prices or other reasonable measures of fair market value,
- h. a description of how the SFI relates to the research and the basis for the determination that the SFI conflicts with the research, and
- i. a description of the key elements of the management plan, including:
 - i. role and principal duties of the conflicted investigator in the research project;
 - ii. conditions of the management plan,
 - iii. how the management plan is designed to safeguard objectivity in the research project;
 - iv. confirmation of the investigator's agreement to the management plan;

- v. how the management plan will be monitored to ensure investigator compliance; and
- vi. other information as needed.

B. Reporting of bias

In the event of an FCOI discovered after an initial FCOI report made to a sponsor, an *ad hoc* committee will have developed a revised management plan, including a mitigation plan, for the new FCOI. OSPR will report the discovery to the sponsor promptly, and in no case later than within 60 days of the discovery. The report will include a description of the impact of the bias on the research, and the actions University has taken, or will take, to eliminate or mitigate the effect of the bias. The Investigator will review the mitigation report and have an opportunity to respond to it within 7 days. The appropriate senior administrator will provide final review and approval for the mitigation report before submission to the sponsor.

8. MAINTENANCE OF RECORDS

All records related to an identified FCOI will be retained at least three (3) years from the date of the final expenditure report submission to the sponsor.

9. ENFORCEMENT, REMEDIES, AND NONCOMPLIANCE

ULM employees can be subject to the disciplinary process of the University if they fail to fully and truthfully disclose financial conflict of interest situations or fail to comply with any stipulated plan for managing the disclosed FCOI.

If the noncompliance of an investigator with this policy or a FCOI management plan appears to have biased the design, conduct or reporting of NIH-, NSF- or PHS-sponsored research, OSPR will promptly notify the funding agency of the noncompliance and of corrective action taken or to be taken.

ULM will comply with PHS regulations regarding an unmanaged or unreported FCOI related to PHS-funded clinical research evaluating the safety or effectiveness of a drug, medical device, or treatment, in the event that any University investigator participates in such research and fails to comply with this policy. These regulations include disclosure of the FCOI in each public presentation of the results of the research, and the request of an addendum to previously published presentations.

10. SUBRECIPIENT REQUIREMENTS

In instances where University issues a subaward on a PHS award, ULM will include language in the subaward document, which instructs the investigator(s) at the subrecipient organization to comply with PHS regulations regarding financial conflict of interest. This can be achieved by either

- A. providing certification from the subrecipient that its FCOI policy complies with the regulation; or
- B. by the subrecipient agreement to report identified FCOIs for its investigators prior to the expenditure of any subaward funds, and no later than 45 days after execution of the subaward document; or
- C. by the subrecipient investigators providing disclosures to ULM, in order to participate in the ULM FCOI disclosure and management process.

11. PUBLIC ACCESSIBILITY REQUIREMENTS

This policy is available to all ULM personnel through University's policy database at <https://webservices.ulm.edu/policies/index.php>, and to the general public via external OSPR website, at <http://ulm.edu/research/policies/SFIFCOI.pdf>

Identified FCOIs held by senior/key personnel, will be made publicly available on the external OSPR website, at <http://ulm.edu/research/fcoi.html>. Postings of identified FCOIs will include the following information: the investigator's name, title and role on the project, the name of the entity in which the SFI is held, the nature of the SFI, and the approximate dollar value of the SFI, within these ranges; \$0 - \$4999, \$5000 - \$9999, \$10,000 – 19,999, \$20,000 - \$39,999, \$40,000 – \$59,999, \$60,000 - \$79,999, \$80,000 - \$99,999, \$100,000 - \$149,999, \$150,000 - \$200,000, and greater than \$200,000. If the interest is one whose value cannot be readily determined through reference to public prices or other reasonable measures of fair market value, then that will be so noted.

Postings of identified FCOIs will be updated annually, and/or within 60 days of a newly identified FCOI. Postings will remain available for three years from the date of the most recent update.

Policy References:

- Public Health Service Policy Promoting Objectivity in Research at <http://grants.nih.gov/grants/policy/coi/> and <http://www.gpo.gov/fdsys/pkg/FR-2011-08-25/pdf/2011-21633.pdf>
- National Science Foundation Investigator Financial Disclosure Policy at <http://nsf.gov/pubs/stis1996/iin117/iin117.txt>
- University of Louisiana at Monroe Financial Conflict of Interest Policy dated October 13, 2008.

Review Process:

Distribution:

Department Heads
Deans
Director of Graduate School
Sponsored Programs and Research
Controller
Budget Officer
Chief Business Officer
Executive Vice President
Vice President of Student Affairs