

SECTION: 1. General

SUBJECT: Financial Conflict of Interest

Background: The purpose of this policy is to give guidelines on what constitutes a conflict of interest, and to ensure outside interests do not conflict or interfere with commitments to LC State.

Point of Contact: Vice President for Finance and Administration & Vice President for Institutional Research, Planning and Effectiveness

Other LC State offices directly involved with implementation of this policy, or significantly affected by the policy: Provost/Vice President for Academic Affairs, Office of Grants & Contracts

Date of approval by LC State authority: August 2022

Date of State Board Approval: n/a

Date of Most Recent Review: n/a

Summary of Major Changes incorporated in this revision to the policy: New Policy

1. Purpose of the Policy

- A. The College has a responsibility to manage, reduce, or eliminate any actual or potential conflicts of interest that may be presented by a financial interest of an investigator, who is seeking, or who has been awarded, research funded by the Public Health Service (PHS) and NIH. In addition, Investigators must ensure that their outside obligations, financial interests, and activities do not conflict or interfere with their commitment to LC State.

2. Who does this policy apply to?

- A. This policy applies to all employees doing PHS/NIH research and is supplemental to [LC State's Conflict of Interest/Code of Ethical Conduct](#).

3. Public Health Service Funding/NIH Funding

- A. The Public Health Service (PHS) has enacted a regulation stating that an investigator cannot have a significant financial interest that might impact his or her objectivity in their research unless they disclose it to LC State's Office of Grants and Contracts (OGC) and create a management plan.

For example, a researcher cannot own stock in a pharmaceutical company while also getting NIH funding to research the invention of a prescription drug that would increase the value of the company that they own interest in unless they disclose it. That financial conflict of interest could create the possibility that their research objectivity is compromised.

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4. Who does this apply to?

- A. An investigator and the spouse or dependent children of an investigator. An investigator refers to the Project Director/Principal Investigator (PD/PI) and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of NIH-funded research, including students, subgrantees, contractors, consortium participants, collaborators, or consultants.

5. What is a financial conflict of interest (FCOI)?

- A. A financial conflict of interest is a significant financial interest that could directly and significantly affect the design, conduct, or reporting of funded research, or the performance of duties and responsibilities performed on behalf of LC State.

6. What is a significant financial interest (SFI)?

- A. Defined by the PHS regulations on Promoting Objectivity in Research (42 C.F.R. 50 subpart F) ([https://www.ecfr.gov/current/title-42/chapter-I/subchapter-D/part-50/subpart-F#p-50.603\(Significant%20financial%20interest\)](https://www.ecfr.gov/current/title-42/chapter-I/subchapter-D/part-50/subpart-F#p-50.603(Significant%20financial%20interest))) and includes the following:
 - 1. The value of any remuneration received from an external entity at present or in the 12 months preceding the disclosure that when aggregated for the investigator and family members totals or exceeds \$5,000. The \$5,000 threshold also applies to salary, royalties, and other payments aggregated for the investigator and family members.
 - 2. The value of a publicly traded equity (plus any remuneration) meets or exceeds \$5,000.
 - 3. Any level of ownership in a privately held equity regardless of the dollar value.
 - 4. Intellectual property rights (e.g., patents, trademarks, copyrights, licensing agreements, and royalties from such rights.)
 - 5. Any other relationships that might present a conflict of interest, such as fiduciary interests (paid or unpaid positions as director, officer, or other management role in a for-profit or not-for-profit entity sponsoring or related to the research) or interests in which compensation or the value of equity or property rights or the combination of interests might affect the outcome of the research.
 - 6. 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; provided, however, that this disclosure requirement does not apply to travel that is reimbursed or sponsored by a federal, state, or local government agency, an Institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education.

7. The following list of SFI's are exempt from the disclosure requirements:

- A. Salary, royalties, or other remunerations paid by LC State;
- B. Income from investment vehicles (mutual funds or retirement accounts that are not managed directly by the individual);

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- C. Income from seminars, lectures, or teaching engagements sponsored by a Federal, state, or local government agency, an Institution of higher education as defined by 20 U.S.C. 1001(a); an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education;
- D. Income from service on advisory committees or review panels for a Federal, state, or local government agency, or an Institution of higher education as defined by 20 U.S.C. 1001(a). (e.g., NIH review panel)

8. When does the FCOI disclosure need to be made?

- A. Disclosures are required to be submitted to the LC State Office of Grants and Contracts (OGC) prior to the submission of a PHS/NIH sponsored proposal.
- B. Investigators new to the college must disclose significant financial interests prior to disbursement of federal funds.
- C. Subsequent to the initial disclosure, investigators must submit updates annually during the period of the award.
- D. If the Investigator acquires a significant financial interest during the course of the year between annual disclosures, the Investigator must report it to the LC State Office of Grants and Contracts (OGC) office within 30 calendar days.

9. What is the disclosure process?

- A. Investigators must submit a completed **Financial Conflict of Interest Disclosure Form** to the Office of Grants and Contracts (OGC). If answering yes to any SFI, the investigator must complete the **Financial Interest Disclosure form 2**.
- B. OGC will also provide a mandatory financial conflict of interest training to all LC State sponsored investigators applying for PHS/NIH funding.
- C. Principal Investigator Responsibilities
 - 1. The principal investigators are responsible for ensuring and certifying that each key personnel on a PHS/NIH proposal has disclosed his/her SFIs. They are also responsible for ensuring and certifying that each investigator has completed the mandatory FCOI training.
- D. Institutional Responsibilities
 - 1. The Office of Grants and Contracts (OGC) will collect and perform an initial review of all disclosed SFIs to determine if an FCOI exists. The OGC may submit an FCOI to a committee for review in complex cases. After a determination is made by the OGC that there may be a potential or actual FCOI, the OGC, in conjunction with a conflict of interest management (CIM) committee will develop a management plan (see below) to address the FCOI.

10. What is a financial conflict of interest management plan?

- A. If an investigator has a financial conflict of interest, the conflict of interest management (CIM) committee will create a management plan. This will be a written plan to eliminate or manage the financial conflict of interest.

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- B. The financial conflict of interest management committee consists of the Vice President for Institutional Research, Planning and Effectiveness, the Grants Coordinator, and the Vice President for Finance and Administration.
- C. These plans will be developed collaboratively with the PI/PD and examples of conditions or restrictions that may be employed to manage conflicts include but are not limited to:
 - 1. Public disclosure of significant financial interests (e.g., when presenting or publishing the research), if appropriate to the discipline;
 - 2. Disclosure of significant financial interests directly to participants involved in human research;
 - 3. Appointment of an independent monitor capable of taking measures to protect the design, conduct, and reporting of research;
 - 4. Modification of the research plan;
 - 5. Change of personnel or personnel responsibilities or disqualification from participation in all or a portion of the research;
 - 6. Reduction or elimination of the financial interest (e.g., sale of an equity interest);
 - 7. Severance of relationships that create the actual or potential conflict of interest; or
 - 8. If it proves impossible to develop an acceptable management plan, funds will be returned to the sponsor.

11. If an investigator has an FCOI and is working on research involving human subjects, then the IRB must be notified of any management plan.

A. Appeals

An investigator may appeal the CIM 's recommendation to the Provost. An investigator dissatisfied with his/her appeal may submit his/her disagreement in writing to the Provost for final resolution.

12. Reporting

- A. Prior to expenditure of any funds, or within 60 calendar days for any interest that LC State identifies as conflicting subsequent to LC State's initial report under a PHS-funded research project, LC State must provide the PHS Awarding Component (via the eRA Commons FCOI Module) with a Financial Conflict of Interest (FCOI) report regarding the related FCOI and implemented Management Plan. This report must include the following information:
 - 1. Grant/Contract Number
 - 2. Project Title
 - 3. Project Director Principal Investigator (PD/PI) or contact PD/PI
 - 4. Name of investigator with FCOI
 - 5. Nature of the FCOI (e.g., equity, consulting fees, or honoraria)
 - 6. Whether the financial interest was managed, reduced, or eliminated
 - 7. Value of the financial interest Financial Conflict of Interest
 - 8. Description of how FCOI relates to PHS-funded research and the basis for the College's determination that the financial interest conflicts with such research
 - 9. Key elements of the Management

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13. Annual updates are also required for the duration of the research project and must include:

- A. Status of the FCOI
- B. Changes to the management plan

14. Retrospective Review

- A. Identification of untimely or any delayed disclosure of an SFI by an investigator requires LC State's review within 60 days of determination, if it is related to PHS-funded research and if an FCOI exists. Determination that there is an unmanaged FCOI requires:
 - 1. Implementation – at least in the interim – of a management plan that specifies the actions that have been and will be taken to manage the FCOI moving forward; and
 - 2. Completion of a retrospective review of the Investigator's activities and the PHS-funded research to determine whether any PHS-funded research, or a portion of it, conducted during the noncompliance period was biased in the design, conduct or reporting of such research within 120 days of the Investigator's noncompliance. Such noncompliance may have occurred due to the Investigator's failure to disclose an SFI deemed an FCOI, LC State's failure to review or manage said FCOI, or the Investigator's failure to comply with a management plan.

15. Mitigation Report

- A. As appropriate, LC State shall update a previously submitted FCOI report specifying the actions taken to manage the FCOI moving forward. If LC State determines there was bias, it must notify the PHS awarding component promptly and submit a mitigation report to that component. The mitigation report must include:
 - 1. The key elements documented in the retrospective review and a description of the impact of the bias on the research project and the institution's actions/action plan to eliminate or mitigate the effect of the bias
 - 2. Subsequently the institution will submit annual reports, as per the regulation. Depending on the nature of the FCOI the institution may decide that additional interim measures are necessary regarding the Investigator's participation in the PHS-funded research project between the date of the FCOI or the Investigator's noncompliance is determined and the completion of the institution's retrospective review.

16. Violations of the Policy May Result in Sanctions

- A. Violations of this policy, such as willful concealment of financial interests, may result in sanctions being imposed upon the violating individual. The conflict of interest management committee will review allegations of violations and will make recommendations regarding the imposition of sanctions to the Provost who will then make a recommendation to the President. The decision of the President with regard to the imposition of sanctions shall be final.

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17. Public Accessibility In accordance with PHS/NIH regulations

- A. LC State will respond to requests regarding financial conflicts of interest by written response within five business days of a request. The response shall include the Investigator's name, position relative to the research project, the name of the entity in which the SFI is held, nature of the SFI, approximate dollar value of SFI, or a statement that the value cannot be readily determined.

18. Records

- A. All financial disclosures and all written documentation on action taken by the Institution to manage conflicts of interest shall be retained until three (3) years after the later of the termination or completion of the award to which they relate, or the resolution of any government action involving those records.

19. Subrecipients

- A. For PHS research that involves subcontractors, subgrantees or subawardees (collectively "subrecipients") at other institutions, LC State requires written agreement terms from subrecipients that they have a conflict of interest policy that conforms to the requirements of all applicable regulations, including time periods to meet disclosure and/or financial conflict of interest (FCOI) reporting requirements.
- B. If any subrecipient does not have such a conflict of interest policy, then LC State shall require that Subrecipient follow LC State's policy, and Subrecipient's failure to promptly do so upon request from LC State shall be considered to be grounds for immediate termination by LC State of any applicable subcontract or subaward. Any written agreement terms required by LC State shall contain the provision that Subrecipients will report to LC State as the awardee Institution, any identified FCOI in sufficient time to allow LC State to report the FCOI to meet its reporting obligations.

20. Financial Conflict of Interest Training

- A. The LC State Office of Grants and Contracts will offer training on Financial Conflicts of Interest to all investigators writing PHS proposals.
- B. All LC State investigators funded by PHS must comply with the following training requirements:
 - 1. Complete FCOI training provided by OGC prior to the submission of a PHS/NIH sponsored proposal and/or the expenditure of funds for any funded project.
 - 2. Thereafter training must be completed at least every four years and immediately when:
 - a. LC State Financial Conflict of Interest policies change in a manner that affects investigator requirements.
 - b. An investigator is new to LC State.
 - c. LC State finds that an investigator is not in compliance with this Financial Conflict of Interest policy or a management plan.