

LAWRENCE UNIVERSITY FINANCIAL CONFLICT OF INTEREST POLICY FOR FEDERALLY-FUNDED RESEARCH

A. PURPOSE

Federal regulations require Lawrence University to maintain a policy for identifying, managing, and disclosing financial conflicts of interest that may affect research funded in part or whole by federal grants. The purpose of such policies is to promote objectivity in research and set expectations among Investigators, institutions, and the public that the integrity of the research enterprise is untainted by Investigators' actual or potential considerations of personal financial gain.

This policy sets out the obligations of Lawrence University (LU) and its Investigators, in fulfillment of the Financial Conflict of Interest (FCOI) guidelines promulgated by the National Institutes of Health and National Science Foundation.

It is important to note that the process of identifying and managing FCOIs begins during the proposal preparation stage, and continues throughout the life of a federal grant.

B. DISCLOSURE OF SIGNIFICANT FINANCIAL INTERESTS

Who must disclose

Each Investigator associated with a research project funded, or proposed for funding, by a federal agency is subject to this policy and must make the required disclosures. The disclosures include information about financial interests of the Investigator and the Investigator's spouse and dependent children.

Investigator means any principal Investigator (PI), co-PI, project director (PD), co-PD, or any other person—regardless of title or position—who is responsible for the design, conduct, or reporting of research funded, or proposed for funding, by NIH, NSF, or other federal agency. In some circumstances, this may include collaborators or consultants.

Note: In general, undergraduates who participate in research or research training as part of a faculty member's program of research are not considered Investigators. While undergraduates often carry out research activities under the supervision of an Investigator, they rarely have sufficient discretion to be considered *responsible* for the design, conduct, or reporting of federally-funded research. However, in the event an undergraduate's role is such that he or she can be considered an Investigator, that undergraduate shall be subject to this policy.

When disclosures must be made

Each Investigator subject to the policy must submit a written disclosure of Significant Financial Interests, if any:

- before a federal research proposal is submitted; and
- annually—in January, or at another time to be determined by the VP for Finance and Administration (VPFA) or his delegate—within the period of the federal award, including any extensions; and
- within 30 days of discovering or acquiring a new Significant Financial Interest within the period of the federal award, including any extensions.

What must be disclosed

Each Investigator subject to the policy must disclose all Significant Financial Interests (SFIs)—their own, as well as those of any spouse and dependent children—that reasonably appear to be related to the Investigator’s institutional responsibilities. Investigators should use a Financial Disclosure Form, to be provided by the Corporate, Foundation, and Sponsored Research Support office (CoFo), to make any disclosures required under this policy.

Institutional responsibilities includes teaching, research, committee service, and other professional work undertaken on behalf of LU.

Significant Financial Interests (SFIs) include things of monetary value (whether or not the value is readily ascertainable) received or owned by the Investigator or by the Investigator’s spouse or dependent children. For all SFIs described below, the aggregated value of interests received or owned by the Investigator, the Investigator’s spouse, and the Investigator’s dependent children should be used to determine whether disclosure is necessary and what information to disclose.

Types of SFIs include: equity in publicly or privately held companies, salary or other payments for services; reimbursed or sponsored travel; and intellectual property rights.

- 1) With regard to any *publicly traded entity*, a Significant Financial Interest exists if the combined value of any equity interest as of the date of disclosure and remuneration received from the entity in the twelve months preceding the disclosure, when aggregated, exceeds \$5,000.
 - a) 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.
 - b) Remuneration includes salary and any payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorship).
- 2) With regard to any *non-publicly traded entity*, a Significant Financial Interest exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure if the aggregate amount of remuneration exceeds \$5000. In addition, any equity interest—regardless of the dollar value or percent ownership stake—constitutes an SFI.
- 3) Income (e.g., royalties) from intellectual property rights and interests (e.g., patents, copyrights), except that covered under Exception #1 (below).
- 4) Sponsored or reimbursed travel related to the Investigator’s institutional responsibilities, except for travel covered under Exception #4 (below).

Exceptions. The term Significant Financial Interest does not include the following:

- 1) Salary, stipends, royalties, or other remuneration paid by LU to Investigators employed or appointed by LU. This includes any intellectual property rights assigned to LU and agreements to share in royalties related to such rights.
- 2) Income from investment vehicles, such as mutual funds and retirement accounts, need not be disclosed so long as the Investigator does not directly control the investment decisions made in these vehicles.
- 3) Income from seminars, lectures, or teaching engagements sponsored by—or services on advisory committees or review panels for—a federal, state, or local government, institution of higher education, academic teaching hospital, medical center, or research institute that is affiliated with an institution of higher education.

- 4) Travel that is reimbursed or sponsored by LU, or by a federal, state, or local government, institution of higher education, academic teaching hospital, medical center, or research institute that is affiliated with an institution of higher education.

Lawrence University recognizes that this policy will require some Investigators to divulge personal financial information. All disclosures made under this policy will be handled with appropriate sensitivity. The VPFA and CoFo staff will keep disclosed financial information as confidential as possible and will share it with others only to the extent the VPFA deems necessary to carry out the required reviews and determinations.

C. DETERMINATION AND MANAGEMENT OF FCOIS

Disclosures made under this policy will be reviewed by the Vice President for Finance and Administration (VPFA). The VPFA is responsible for reviewing each disclosed SFI and reasonably determining:

- (1) Whether the SFI is related to the federally-funded research: i.e., whether it could be affected by the federally-funded research or is an entity whose financial interest could be affected by the research. The VPFA may involve the Investigator in this review.
- (2) If the VPFA determines an SFI is related to the federally-funded research, the VPFA shall then reasonably determine whether the SFI could directly and significantly affect the design, conduct, or reporting of the federally-funded research (i.e., whether the SFI is a Financial Conflict of Interest).

For an initial disclosure, this review should take place prior to any expense being charged to the grant fund account. For subsequent disclosures, this review should take place within 60 days.

If the VPFA determines that a Financial Conflict of Interest exists, the VPFA shall work with the Investigator (and any others who may be appropriate, such as the Provost, faculty or staff with relevant expertise, and/or outside experts) to either eliminate the conflict or develop a management plan.

If an FCOI is promptly eliminated (through means such as selling an equity interest, severance of relationships that create financial conflicts, or change of grant personnel or personnel responsibilities), then the FCOI no longer exists and does not need to be reported.

If eliminating the FCOI is not feasible or desirable, a plan shall be developed to manage the conflict. The plan shall include:

- Name, role, and principal responsibilities of the conflicted Investigator.
- Project title and federal award number.
- Explanation of the nature of the FCOI, including the name of the entity with which the conflict exists and the approximate dollar value of the SFI (or a statement that the value is not readily ascertainable).
- Conditions of the management plan and how compliance with these conditions will be monitored.
- Justification of how the management plan is reasonably expected to safeguard objectivity in the design, conduct, and reporting of the research project.
- Confirmation that the conflicted Investigator and the VPFA agree to the plan.
- Other information as determined by the VPFA to be appropriate.

Actions that may be specified in the management plan to safeguard the integrity of the research enterprise may include, but are not limited to: public disclosure of financial conflicts of interest; divestiture of the financial interest; monitoring of the research by an independent reviewer; modification of the research plan; or change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the research.

LU will report each FCOI and management plan in compliance with the sponsoring federal agency's requirements.

If, for whatever reason, an FCOI is not disclosed or managed in a timely manner and research work has been undertaken while the conflict exists, the VPFA may convene a task force to conduct a retrospective review; to determine whether the FCOI resulted in any bias in the design, conduct, or reporting of federally-supported research; and to recommend a mitigation plan if necessary. This retrospective review shall be undertaken, and its findings and recommendations reported, in a manner consistent with the requirements of the sponsoring federal agency.

Subrecipients

Lawrence University must take reasonable steps to ensure that all subrecipients comply with applicable federal regulations regarding Financial Conflicts of Interest. To that end, LU will include in written agreements with each subrecipient terms that specify whether this policy, or the applicable policy of the subrecipient's institution, will apply to subrecipient Investigators. If the subrecipient institution's policy will be used, the agreement will further include a certification that the subrecipient institution has adopted and enforces FCOI policies that comply with applicable federal regulation, and will specify the timing of subrecipient reports to LU of identified FCOIs such that LU can timely complete its FCOI report (if any) to the sponsoring federal agency.

D. POLICY ADMINISTRATION AND ENFORCEMENT

A member of the Corporate, Foundation, and Sponsored Research Support staff (CoFo) will provide FCOI training to Investigators, typically in the form of a meeting or workshop. This training will be provided:

- upon award of a new federal research grant, to each Investigator under the grant. This must be completed before the grant-supported research begins.
- to any Investigator who has not participated in FCOI training in the prior four years.
- to all Investigators, any time LU revises this policy or related procedures in a manner that affects the requirements of Investigators.
- an Investigator is new to LU.
- any time LU finds that an Investigator is not in compliance with this FCOI policy or an FCOI management plan.

CoFo will solicit financial disclosures during the proposal development process and annually during the award, and will collect financial disclosure statements on behalf of the VPFA.

Documentation relating to the implementation of this policy—including financial disclosures, the determinations of the VPFA, FCOI management plans, and evidence of plan monitoring—will be maintained as part of the record for each applicable federal research proposal or award for at least three years after the final financial report is submitted. These documents will be treated as confidential records similar to other grant documents containing salary or other personal financial information.

Investigators are required to comply with this policy as a condition of applying for and receiving federal research grants administered by Lawrence University. Investigators failing to comply with this policy may be subject to disciplinary proceedings and sanctions as appropriate under the relevant institutional policies for faculty, staff, or students.

This policy shall be made publicly available on the LU website. Information on identified FCOIs held by senior/key personnel shall be provided by written response to any requestor within five business days of a request.

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