

Lake Forest College
Financial Conflict of Interest Policy for Federal Grants

In accordance with federal regulations, it is the responsibility of Lake Forest College to identify and manage actual or perceived conflicts of interest that may arise in externally---funded research projects. A conflict of interest occurs when an individual's private interests might reasonably be construed to affect his or her independent, unbiased judgment in designing, conducting, managing or reporting federally---funded research. The principal investigator, project directors, and other senior/key personnel are required by the College to disclose Significant Financial Interest (SFI) when applying for federally sponsored external grant funding and at intervals during the award period of a federally---sponsored project.

I. Definitions

“Investigator:” The project director (PD) or principal investigator (PI), or any other person (irrespective of title or position) who is responsible for the design, management, or reporting of federally---funded research or who is proposed for such funding, including collaborators or consultants.

“Senior/Key Personnel:” The PI, PD or any other person the College identifies in the federal grant application or various reports as senior or key personnel.

“Institutional Responsibilities:” An investigator's professional responsibilities on behalf of the College which may include, but are not limited to, research, teaching, institutional committee memberships, and service on panels (e.g., an Institutional Review Board or Human Subjects Review Board)

“Financial Interest:” Anything of monetary value whether or not that value is readily ascertained.

“Significant Financial Interest:” A significant financial interest (SFI) consists of one of the following interests of the Investigator (or the Investigator's spouse, domestic partner, and/or dependent children) if the interest reasonably appears to be related to the Investigator's institutional responsibilities:

- a. With respect to any publicly-- - traded entity, a significant financial interest exists if the value of any remuneration received from the entity in the twelve (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 U.S. For purposes of this definition, 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 measure of fair market value;

- b. With respect to any non---publicly traded entity, a significant financial interest exists if the value of any remuneration received from the entity in the twelve (12) months preceding the disclosure, when aggregated, exceeds \$5,000 U.S., or when the Investigator, the Investigator's spouse, domestic partner, and/or dependent children holds any equity interest (e.g., stock, stock option, or other ownership interest); or
- c. Intellectual property rights and interests (e.g., patents and copyrights) upon receiving income related to such rights and interests.
- d. Investigators must also disclose the occurrence of any reimbursed or sponsored travel (i.e., travel paid on behalf of the Investigator, and not reimbursed to the Investigator, such that the exact monetary value might not otherwise be readily available) related to their institutional responsibilities, provided this disclosure does not apply to travel reimbursed or sponsored by a federal, state, or local government agency located in the United States, a United States Institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with a United States Institution of higher education. This disclosure must include at a minimum a statement of the purpose of the trip, the identity of the sponsor, the destination, and the duration of the trip.

3. Significant Financial Interest *does not include* the following:

- Salary, royalties or other remuneration the College pays to the Investigator if the Investigator is employed or otherwise appointed by the College;
- Intellectual Property Rights assigned to the College and agreements to share in royalties related to such rights;
- Income from such investment vehicles as mutual funds and retirement accounts provided the Investigator does not directly control the investment decisions made for these vehicles;
- Income from seminars, lectures, or teaching engagements sponsored by a federal, state, or local government agency located in the United States, a United States Institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with a United States Institution of higher education; or income from service on advisory committees or review panels for a federal, state, or local government agency located in the United States, a United States Institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with a United States Institution of higher education;
- Income from service on advisory committees or review panels for a federal, state, or local government agency located in the United States, a United States Institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with a United States Institution of higher education.

“Financial Conflict of Interest” (FCOI): A Significant Financial Interest that could directly or indirectly affect the design, management, or reporting of federally---funded research.

“Family Member:” A spouse, parents, siblings, children, or any other relative if the latter resides in the same household as the trustee or employee.

II. Investigator Training

Lake Forest College will provide training on its Financial Conflict of Interest policy and the investigator’s responsibilities regarding the disclosure of SFIs. The College’s FCOI training must be completed by each Investigator:

- Prior to engaging in research related to a federally--- funded project;
- At least every four years; and
- Immediately when any of the following circumstances apply:
 - The College revises its policy in a manner that affects the investigator;
 - An investigator is new to the College; or
 - The College determines that an investigator is not in compliance with the College’s FCOI policy.

The College requires that each Investigator complete the FCOI Online Tutorial offered by the NIH’s Office of Extramural Research and submit his/her Certificate of Completion to the Office of Sponsored Research prior to completing the Financial Conflict of Interest Disclosure form, which is described further in Section III.

III. Significant Financial Interest (SFI) Disclosure

Each Investigator must disclose SFIs at the time of application for federal grant funding. The Investigator will complete the Financial Conflict of Interest Disclosure form and submit it to the Office of Grants and Sponsored Research (OGSR), which will collect the form on behalf of the Dean of the Faculty (hereinafter “the Dean”). Any co-investigators must also complete the Financial Conflict of Interest Disclosure form and return it to OGSR. In all instances Investigators and any co-investigators must complete and present certification of completion of NIH’s FCOI Online Tutorial to OGSR before completing a Financial Conflict of Interest Disclosure form.

Investigators must also update their significant financial disclosures at prescribed intervals during the award period of a federally sponsored project. OGSR collects these disclosures on behalf of the Dean. Additionally, the Investigator must report any changes in reportable SFIs within 30 days of discovering or acquiring (e.g., through purchase, marriage, or inheritance) such interests. OGSR will also request financial disclosure updates from Investigators at the time of annual project reporting.

If in the course of an ongoing, federally---funded project an Investigator who is new to the project discloses a significant financial interest or an existing Investigator discloses a new significant financial interest, the College will within 60 days review the SFI, determine if an FCOI exists, and implement an interim management plan. If the College identifies an SFI that was not disclosed or reviewed in a timely fashion, the Dean of the Faculty shall within 60 days review the SFI, determine if an FCOI exists, and implement an interim management plan.

IV. Management of Financial Conflicts of Interest

The Dean will perform a review of all SFI disclosures to determine (1) whether an Investigator's SFI is related to federally---funded research and if it is, (2) whether the SFI is a financial conflict of interest. An Investigator's SFI is deemed related to federally---funded research when the Dean reasonably determines that the SFI could be affected by the federally funded research project or resides within an entity whose financial interest could be affected by the research. Thus, a financial conflict of interest exists when the Dean (and the College) reasonably determines that the SFI could directly or indirectly affect the design, management, or reporting of the research project.

If it is determined that an SFI exists that could directly or indirectly affect the design, management, or reporting of the research project, the Dean will implement an *interim management* plan that details proposed steps to manage the financial conflict of interest. The College will monitor the Investigator's compliance with the interim management plan on an ongoing basis until the completion of the project.

1. Key elements of the Interim Management Plan

At minimum the interim management plan shall include:

- Role and principal duties of the research project's conflicted Investigator;
- Conditions of the interim management plan;
- Description of how the plan is designed to safeguard objectivity in the research project;
- Confirmation of the investigator's agreement to the plan;
- Description of how the plan will be monitored to ensure Investigator compliance; and
- Other information as needed.

2. Key conditions or restrictions included in the Interim Management Plan

- Public disclosure of financial conflicts of interest, e.g., when presenting or publishing the research;
- Disclosure of financial conflicts of interest to participants for research projects involving human subjects;
- Appointment of an independent monitor capable of taking measures to protect the design, management, and reporting of the research against bias resulting from the financial conflicts of interest;
- Modification of the research plan;
- Change of personnel or their responsibilities, or disqualification of personnel from participation in a portion or all of the research;
- Reduction or elimination of the financial interest, e.g., sale of an equity interest; or
- Severance of relationships that create financial conflicts.

Should the sponsoring agency decide that a particular FCOI will likely bias the objectivity of the research, the sponsoring agency may impose special award conditions, suspend funding, or impose other enforcement mechanisms until the matter is resolved.

In all instances where an FCOI is not identified or managed in a timely way, including failure by the Investigator to disclose an SFI, failure by the College to review or manage an FCOI, or an Investigator's failure to comply with an interim management plan, the College shall, within 120 days of the date of noncompliance determination, complete a retrospective review of the investigator's activities and the project to determine whether there is bias in the design, management, or reporting of the related research. If the College finds evidence of bias, the College will complete a mitigation report describing the impact of the bias on the project and the College's plan of action for eliminating or mitigating the effect of the bias.

V. Financial Conflict of Interest (FCOI) Reporting

Prior to the expenditure of funds, the College will provide an FCOI report and the assurance to federal sponsors of externally-funded research that an interim management plan will be implemented if necessary. In the instance that an FCOI is detected during the project period or an Investigator who is new to the project arrives with an FCOI, the College will provide a report to the federal sponsor within 60 days of the FCOI's identification and make assurances that an interim management plan will be implemented.

In the instance that an SFI report was not disclosed or reviewed in timely fashion, the College will require a retrospective review and the Dean will notify the federal sponsoring agency if bias is found and will complete a mitigation report for the project.

The College will annually update the status of previously identified FCOIs, noting also any changes made to the associated interim management plans. The status update report will be submitted at the same time as the annual FCOI report.

Public accessibility: Information concerning any FCOI held by Senior/Key personnel will be made available within five days of receiving a written request when:

- a. the disclosed SFI is still held by the Investigator;
- b. the SFI is determined to be related to the project; and
- c. the SFI is deemed to be a Financial Conflict of interest.

This information will also be made available prior to expenditure of funds and will be updated per the College's FCOI policy.

All records of disclosures of financial interests and the College's review of, and response to, such disclosures (whether or not a disclosure resulted in the determination of an FCOI) and all actions under the College's FCOI policy or retrospective review, will be retained for at least three years from the date of submission of the final expenditures report or the resolution of any federal sponsor action involving those records, whichever occurs later.

VI. Subrecipients and Significant Financial Interest

If a subrecipient relationship is established, terms will be included in the written agreement establishing whether the College's FCOI policy or the policy of the subrecipient's institution will apply to subrecipient investigators. Subrecipients using their own policy must adhere to a specific schedule for reporting all identified conflicts of interest to the College, provide certification that their institution is in compliance with federal guidelines regarding SFI disclosure, and make assurances that their portion of the project is compliant with their institutional policies. In all instances the College will report any FCOIs on the part of the subrecipient to the project's awarding agency.