

FINANCIAL CONFLICT OF INTEREST (FCOI) POLICY IN RELATION TO SPONSORED PROJECTS

These guidelines define the general University policy and procedures regarding conflicts of interest in relationship to sponsored projects involving research, education, training, construction, community service, and any other activity funded by an award to the University. Their purpose is to preserve the credibility and integrity of the University's faculty and staff so that the public trust and confidence in the University's sponsored activities is ensured.

In accordance with Federal regulations, the University 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. Thus, the University requires that investigators disclose any Significant Financial Interest that may present an actual or potential conflict of interest in relation to a sponsored project.

A potential conflict of interest exists in any situation in which there is a divergence between an individual's private interests and his or her professional obligations to the University such that an independent observer might reasonably question whether the individual's professional actions or decisions are determined by considerations of personal gain, financial or otherwise. The potential for conflict of interest is inherent in the situation and does not necessarily depend on the character or actions of the individual.

A. Definitions

Financial Conflict of Interest (FCOI) means a Significant Financial Interest that could directly and appreciably affect the design, conduct or reporting of sponsored research.

Institutional Responsibilities means the Investigator's professional responsibilities on behalf of the University, including but not limited to activities such as research, research consultation, teaching, professional practice, and service on University panels and committees.

Investigator means the principal investigator/project director, co-principal investigator, and any other person who is responsible for the design, conduct, or reporting of research, educational or other activities funded or proposed for funding by an external sponsor. This may include, for example, collaborators or consultants. In this context, the term "Investigator" includes the investigator's spouse and dependent children.

Manage 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

Senior/key personnel means the Project Director or Principal Investigator, as well as any other person identified as senior/key personnel in a grant application, progress report, or any other report submitted to a sponsoring entity.

Significant Financial Interest means anything of monetary value, including but not limited to the interests listed below, that reasonably appears to be related to the Investigator's Institutional Responsibilities:

1. Salary or other payments for services (e.g., consulting fees, paid authorship or honoraria);
2. Equity interests (e.g., stocks, stock options, or other ownership interests, including interests in non-publicly traded entities);
3. Intellectual property rights (e.g., patents, copyrights and royalties from such rights).
4. The occurrence of any reimbursed travel or sponsored travel related to institutional responsibilities. Sponsored travel is that which is paid on behalf of the Investigator and not reimbursed to the Investigator so the monetary value may not be readily available.

The term does not include:

1. Salary, royalties and other remuneration from the University, where the Investigator is currently employed or otherwise appointed by the University;
2. Income from seminars, lectures, or teaching engagements and service on advisory committees or review panels for 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.
3. 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.
4. 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.
5. Salary, royalties, or other payments, and equity interests, that, when aggregated for the Investigator and his or her spouse or dependent children, do not exceed \$5,000 during the preceding twelve-month period except that any equity interest in a nonpublicly traded entity shall be considered a Significant Financial Interest. Value shall be determined through reference to public prices or other reasonable measures of fair market value.

However, the exclusion in item 5 shall not apply if the compensation or transfer of an equity interest is conditioned upon a particular outcome in a sponsored research project.

B. Guidelines

1. As required by Federal regulations, each Investigator engaging in research related to any Public Health Service (PHS) sponsored grant or contract must complete mandatory training prior to engaging in the research and at least every four years, and immediately under the following circumstances:
 - University FCOI policies change in a manner that affects investigator requirements
 - An investigator is new to the University
 - The University finds an investigator noncompliant with this policy or an FCOI management plan.
2. Each investigator who is planning to participate in sponsored research shall complete a Significant Financial Interest Disclosure Form and submit it, along with any necessary documentation, to the Associate Provost for Research and Sponsored Programs. If the form is being submitted in connection with a new proposal, it must be received by the Office for Research and Sponsored Programs at least two weeks prior to the proposal deadline date established by the sponsoring agency. If an investigator discovers or acquires a new Significant Financial Interest (e.g. through purchase, marriage or inheritance) requiring disclosure after the initial disclosure, he or she should submit the Significant Financial Interest Disclosure Form within two weeks of the acquisition of this new interest. All financial disclosures must be updated by investigators during the period of the award, on an annual basis. Such updates shall include any information not previously disclosed, as well as updates on previously disclosed information, including updates on the value of Significant Financial Interests.
3. Each investigator is required to disclose any Significant Financial Interests on behalf of the Investigator and his or her spouse and dependent children.

Disclosures regarding travel must include the purpose of trip, sponsor/organizer, destination, and duration. The University will determine if further information is needed, including determination or disclosure of monetary value, in order to determine whether the travel constitutes an FCOI.

Regardless of the above minimum requirements, a faculty member or administrator, in his or her own best interests, may choose to disclose any other financial or related interest that could present an actual conflict of interest or be perceived to present a conflict of interest. Disclosure is a key factor in protecting one's reputation and career from potentially harmful allegations of misconduct.

4. The Associate Provost for Research and Sponsored Programs ("Associate Provost") shall solicit disclosures of Significant Financial Interests from each investigator who is

planning to participate in, or is participating in, sponsored research. The Associate Provost shall then review the disclosures to determine if the Significant Financial Interest disclosed is related to sponsored research. A Significant Financial Interest is related to sponsored research when the financial interest could be affected by the sponsored research, or is in an entity whose financial interest could be affected by the research. If the interest is so related, a determination shall be made about whether there is a financial conflict of interest (FCOI). An FCOI exists when the University reasonably determines that the Significant Financial Interest could directly and appreciably affect the design, conduct or reporting of sponsored research.

If a determination is made that there is an FCOI as defined by this policy, then the investigator and the Associate Provost for Research and Sponsored Programs shall negotiate a conflict of interest management plan that is mutually acceptable before the expenditure of any funds under a sponsored project. Such a plan will detail steps to manage, reduce, or eliminate the FCOI presented by a Significant Financial Interest. These steps may include, but are not limited to, one or more of the following:

- a. Public disclosure of FCOIs (e.g. when presenting or publishing the research);
- b. For research projects involving human subjects, disclosures of FCOIs directly to participants
- c. review of research protocols by independent reviewers;
- d. monitoring of research by independent reviewers;
- e. modification of the research plan;
- f. Change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the funded project;
- g. divestiture of Significant Financial Interests;
- h. severance of relationships that create FCOIs.

If the Associate Provost for Research and Sponsored Programs determines that imposing any of the above-referenced conditions or restrictions would be inequitable, or that the potential negative impact that may result from a Significant Financial Interest is outweighed by the interests of scientific progress, technology transfer, and public health or welfare, he/she may recommend that, to the extent permitted by Federal regulations, the project continue without the imposition of such restrictions or conditions.

All proposed management of conflict of interest cases shall be reviewed and approved or amended by the Provost and Senior Vice President for Academic Affairs. In the event that the Associate Provost for Research and Sponsored Programs and the investigator are unable to agree on the terms of management of a conflict of interest, the Provost and Senior Vice President for Academic Affairs will meet with them and attempt to achieve a mutually agreed upon resolution. If such a mutually agreed upon resolution cannot be achieved, then the Provost and Senior Vice President for Academic Affairs will make a final decision regarding the terms of the conflict of interest resolution.

Where in the course an ongoing sponsored project, a new Investigator discloses a Significant Financial Interest, or an existing Investigator discloses a new Significant Financial Interest, the above process will take place within sixty days, and a management plan will be implemented on at least an interim basis. The management plan shall specify the actions that have been, and will be, taken to manage any FCOIs, and, depending on the nature of the Significant Financial Interest, the University may determine that additional interim measures are necessary with regard to the Investigator's participation in sponsored research between the date of disclosure and the completion of the University's review.

5. The approved management plan shall be incorporated into a memorandum of understanding between the University and the Investigator that will detail the conditions and restrictions imposed upon the investigator in the conduct of the project or in the relationship with a business enterprise or entity. The University shall monitor compliance with the management plan on an ongoing basis until completion of the project.
6. Whenever the University identifies a Significant Financial Interest that was not disclosed timely by an Investigator or was not previously reviewed by the University, the Associate Provost shall, within sixty days, review the Significant Financial Interest, determine whether it is related to sponsored research and whether an FCOI exists. If an FCOI exists, the University will implement, on at least an interim basis, a management plan as described in paragraph 4 above.
7. The University will provide initial and ongoing reporting of FCOIs to the appropriate federal entity. The FCOI reports shall include all information required by federal regulations.
8. As required by Federal regulations, all identified FCOIs will be made available via a written response to all requestors within five business days of receipt of a request if the FCOI is held by senior/key personnel.
9. In the event that the conflict of interest cannot be satisfactorily resolved at the time an award notice is issued by a Federal sponsor, the University will disclose this fact to the sponsoring agency prior to the expenditure of any funds under the award. The Federal sponsoring agency will also be notified of unresolved conflicts of interest that arise during the project period. In the case of non-Federal sponsors, the University shall reserve the right to notify these sponsors of unresolved conflicts of interest.
10. Records of Investigator financial disclosures, the University's review of, and response to, these disclosures, and all actions taken to manage FCOIs under this policy shall be retained by the Office for Research and Sponsored Programs until at least three years from the submission of the final expenditure report, or until the resolution of any government action involving those records, whichever is longer.

11. The University will conduct a retrospective review where the above process has not been followed and an FCOI is not timely identified or managed. Such review will occur within 120 days of determination of noncompliance, and will determine whether any sponsored research was biased in design, conduct, or reporting. The retrospective review shall be documented as required by federal regulations, and, if appropriate, the previously submitted FCOI report shall be updated. If bias is found, the University must notify and submit a mitigation report to the appropriate federal entity, as required by federal regulations. The report must include the impact of the bias on the research project and the actions the University has taken, or will take, to eliminate or mitigate the effect of the bias.
12. If an investigator violates this financial conflict of interest policy or the terms of an executed Memorandum of Understanding, the University shall institute disciplinary procedures as detailed in Faculty Policy Series #41 (2012).
13. Subrecipient institutions/investigators from other institutions must either comply with this policy or provide certification that their institutions are in compliance with Federal FCOI laws, rules, and regulations and that they are in compliance with their institution's FCOI policy.

All subrecipient agreements shall include terms that establish whether the University's FCOI policy or the subrecipient FCOI policy shall apply to the subrecipient's Investigators.

- a. If the subrecipient's Investigators must comply with the subrecipient's FCOI policy, the subrecipient agreement must specify the time period for the subrecipient to report all identified FCOIs to the University. This time period shall be sufficient to enable the University to provide timely FCOI reports in accordance with federal regulations.
 - b. If the subrecipient's investigators must comply with the University's FCOI policy, the subrecipient agreement must specify time periods for the subrecipient to submit all Investigator disclosures of Significant Financial Interests to the University, which time period shall be sufficient to enable the University to timely comply with its review, management, and reporting obligations under federal regulations.
14. The provisions of the Hofstra University Conflict of Interest and Commitment Policy shall also apply to any investigator participating in sponsored research.