



Suffolk University

Office of Research and
Sponsored Programs

Suffolk University Financial Conflict of Interest in Federally Funded Research Policy

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Suffolk University
Financial Conflict of Interest in Federally Funded Research Policy

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Suffolk University

Financial Conflict of Interest in Federally Funded Research Policy

I. General Principles

This “Financial Conflict of Interest in Federally Funded Research Policy” (hereinafter referred to as the “Policy”) was crafted in response to federal regulations that require that all investigators to disclose any potential financial conflict of interest to the university prior to undertaking federally funded research. This Policy is applicable to all federally funded sponsored project activity at Suffolk University, including specifically, all projects funded, directly or indirectly, by the Public Health Service of the U.S. Department of Health and Human Services (PHS), other than Small Business Innovation Research (SBIR) or Small Business Technology Transfer (STTR) awards. The Policy was designed to promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct, and reporting of research funded by federal grants or cooperative agreements will be free from bias resulting from investigator financial conflicts of interest.

The following definitions apply to this policy unless a specific federal policy uses a different definition, in which case that agency's definition will apply:

- Collaborative Institutional Training Initiative (CITI): means a subscription service that provides research ethics education to all members of the research community.
- Conflict of Interest: the situation in which personal considerations have the potential to compromise or bias professional judgment and objectivity.
- Disclosure of significant financial interests: means an investigator's disclosure of significant financial interests (SFI) to Suffolk University.
- Financial Conflict of Interest (FCOI): means a significant financial interest (SFI) that could directly and significantly affect the design, conduct, or reporting of federally funded research.
- Financial Interest: means anything of monetary value, whether or not the value is readily ascertainable.
- Investigator: the project director (PD) or principal investigator (PI), co-principal investigator (Co-PI), and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of federally funded research, which may include, for example, collaborators or consultants.
- Institutional Responsibilities: means an Investigator’s professional responsibilities on behalf of and as defined by the University, including but not limited to, activities such as research, research consultation, teaching, professional practice, institutional committee memberships, and service on panels such institutional review boards.

- **Management Plans:** means actions taken by the University to address a 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.
- **Public Health Service (PHS):** means the operating division of the Health and Human Services Department (HHS) responsible for promoting the protection and advancement of physical and mental well-being, and any components of the PHS to which the authority involved may be delegated, including the National Institutes of Health (NIH).
- **Research:** means a systematic investigation, study or experiment designed to develop or contribute to generalizable knowledge relating broadly to public health, including behavioral or social-sciences research. The term encompasses basic and applied research and product development. As used in this policy, the term includes any such activity or sponsored program for which funding is available from a federal agency through a grant or cooperative agreement, such as a research grant, career development award, center grant, individual fellowship award, infrastructure award, training grant, program project, or research resources award.
- **Senior/Key Personnel:** means the PD/PI and any other person identified as Senior/Key Personnel by the University in the grant application, progress report, or any other report submitted on the research to the federal funding agency by the University under the scope of this policy. All of the following may be considered senior/key personnel, to the extent they are responsible for the design, conduct or reporting of the research:

- Professional faculty
- Research associates
- Emeritus faculty
- Sub-recipient personnel
- Research collaborators
- Visiting scientists
- Individuals with courtesy appointments
- Undergraduate, graduate, and post-doctoral students

II. Significant Financial Interest

A significant financial interest (SFI) exists if the following situations apply to the investigator and/or the investigator's spouse and dependent children, involving companies that reasonably appear to be related to the investigator's institutional responsibilities:

For publicly traded companies, if income in excess of \$5000 (in the aggregate) is received during the twelve months preceding the disclosure. Examples of income include salary, consulting fees, honoraria, paid authorship, stock, stock options, or other ownership interests (based on public prices or other reasonable measures of fair market value).

For non-publically traded companies, if income in excess of \$5000 (in the aggregate) is received during the twelve months preceding the disclosure, or when any equity interest is held (e.g., stocks, stock options, or other ownership interests).

If any income is received from intellectual property rights and interests (e.g., patents, copyrights).

Any travel paid for by any entity other than a federal, state or local government, an institution of higher education, an academic teaching hospital, a medical center or a research institute associated with an institution of higher education must be disclosed.

This disclosure will include, at a minimum, the purpose of the trip, identity of the sponsor/organizer, destination, and duration. In accordance with the University's FCOI policy, the Director of the ORSP will determine if further information is needed, including a determination or disclosure of monetary value, in order to determine whether the travel constitutes an FCOI with the federally funded research.

Significant financial interest does not include the following types of financial interests:

Salary, royalties, or other remuneration paid by the University to the investigator if the investigator is currently employed or otherwise appointed by Suffolk, including intellectual property rights assigned to the University and agreements to share in royalties related to such rights

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

Income from seminars, lectures, or other teaching engagements, or from service on advisory panels or review panels from a Federal, state, or local government agency, an institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education

III. Financial Conflict of Interest Review

The Suffolk Research Council (Council) will serve to routinely review FCOI statements. Members of the committee are expected to have demonstrated significant grantsmanship and shall have training and/or experience related to financial conflict of interest.

Council Duties Related to FCOI:

The Council will review the FCOI forms and the associated management/monitoring and either accept or suggest modifications to manage or eliminate the conflict.

The Council will also review complex disclosures, as requested by the Director of the ORSP, to assure that all issues have been considered or addressed.

In addition, the Council will review management plans and make recommendations for resolutions upon a disagreement and will submit their recommendations to the Director of the ORSP.

Recommendation disputes that cannot be resolved with the Director of ORSP, will be presented to the Provost for consideration and final decision making.

IV. Institutional Responsibilities and Procedures

A. Required Disclosures

Annual Disclosure

All Investigators and Senior/Key Personnel must disclose annually to the Director of the ORSP their Significant Financial Interests that could be perceived to be related to any of their institutional responsibilities. In addition, the Investigator must list all Significant Financial Interests of his/her spouse and dependent children that are related to the Investigator's institutional responsibilities. The ORSP has developed a Financial Conflict of Interest Form ("FCOI Disclosure") for the required disclosure.

Interim Disclosure

During the pendency or the term of an award, contract, or cooperative agreement Investigators are required to update disclosures **within thirty (30) calendar days** of discovering or acquiring a new financial interest (e.g., through activity, purchase, marriage or inheritance).

Proposal Disclosure

Each Investigator who is planning to participate in the PHS and/or NSF-funded research must submit the FCOI Disclosure (1) no later than the time of application for PHS and/or NSF-funded research; (2) prior to expending funds for a new award (grant, contract or cooperative agreement); (3) upon joining a project/award/contract team engaged in PHS and/or NSF-funded research; and (4) upon transfer to the University of a PHS and/or NSF -funded award, contract or cooperative agreement.

Reimbursed or Sponsored Travel

Investigators must also disclose, within thirty (30) days of travel, 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.

The details of this disclosure include all the following:

- the purpose of the trip
- the identity of the sponsor/organizer
- the monetary value (to the extent available)
- the destination
- the duration

The 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.

B. Training Requirements

In order to facilitate compliance with the federal policy, the University is responsible for investigator training, collection and evaluation of FCOI forms, and general enforcement of this policy.

In addition to developing this policy and associated forms, training will be provided by ORSP for all investigators prior to engaging in federally funded research. Training must be repeated at least every four years, and immediately when:

- the University revises its FCOI policies or procedures in any manner that affects the requirements of Investigators
- an investigator is new to the University
- or an investigator is found to be in non-compliance with the University's FCOI policy or management plan

The University requires that each Investigator and Senior/Key Personnel complete the Conflict of Interest Training Module that is located on the CITI website (<https://www.citiprogram.org/>).

C. Subcontracts

If federally funded research involves a sub recipient (e.g., subcontractors or consortium members), the University, as the awardee institution, will take reasonable steps to ensure that any sub recipient investigator complies with the federal policies by:

- Establishing in writing with the sub recipient whether the financial conflicts of interest policy of the University or that of the sub recipient will apply to the sub recipient's investigators
- If the sub recipient's investigators must comply with the sub recipient's financial conflicts of interest policy, the sub recipient shall certify that its policy is in compliance with federal policies. In the absence of this certification, the agreement will state that sub recipient investigators are subject to the Financial Conflicts of Interest policy of the University for disclosing significant financial interests that are directly related to the sub recipient's work for the University
- Additionally, if the sub recipient's investigators must comply with the sub recipient's financial conflicts of interest policy, the written agreement will specify a deadline for the sub recipient to report all identified financial conflicts of interest to the University so that the University can provide timely FCOI reports
- Alternatively, if the sub recipient's investigators must comply with the University's financial conflicts of interest policy, the written agreement will specify a deadline for the sub recipient to submit all investigator disclosures of significant financial interests to the University so that the University can provide timely FCOI reports

D. Review of FCOI and Management of Conflicts

A FCOI exists when Suffolk University reasonably determines that the significant financial interest could directly and significantly affect the design, conduct, or reporting of the federally funded research. At the time of submission of a grant to a federal agency, all participating investigators and Senior/Key Personnel are required to fill out and submit a FCOI form along with the proposal and the Proposal Transmittal.

Signed FCOI disclosure forms will be reviewed by Director of the ORSP and the members of the Council. Outcomes may include:

If a FCOI disclosure form indicates no significant financial interest, the forms can be logged and filed.

If a FCOI form indicates a significant financial conflict of interest, the proposal and transmittal form will be forwarded on to the ORSP to meet agency deadlines but with a flag indicating a possible conflict of interest. Financial conflicts of interest will be addressed by one of the following approaches:

- The Dean will work with the investigator to develop a management plan to eliminate the conflict of interest before the FCOI form is forwarded to ORSP. The dean or director will confirm the agreement in writing to the Director of ORSP
- If it is not possible to eliminate the conflict of interest, a plan to reduce or manage the conflict must be developed by the investigator in consultation with the dean or director with guidance from ORSP. This plan will then be forwarded to the Director of ORSP who will forward it on to the Research Council
- All conflicts of interest must be resolved and management plans approved before the research project can begin

If a disclosure of a new conflict arises or the discovery of an undisclosed conflict is uncovered, the Council will review and make recommendations within 60 days of the new conflict disclosure or unreported disclosure discovery.

The Council will review all of the submitted material and either accept or suggest modifications to further eliminate the conflict. This could involve, at either the Council's request or at the investigator's request, a meeting with the Council. Expert opinions may also be sought by the Council.

The Council will submit a recommendation to the Director of the ORSP who will forward it on to the Provost for final approval. Investigators may appeal any final decision in writing within 14 days.

Examples of approaches that could be used to manage a FCOI include, but are not limited to:

- Public disclosure of FCOI (e.g., when presenting or publishing the research)
- For research projects involving human subjects research, disclosure of FCOI directly to 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 in personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the research
- Reduction or elimination of the financial interest (e.g., sale of an equity interest)
- Severance of relationships that create financial conflicts

Whenever the University implements a management plan, the University will monitor investigator compliance with the management plan on an ongoing basis until completion of the affected federally funded research project. In the event of any significant conflicting financial interest that is discovered subsequent to initial reports to federal agencies, the University will implement a management plan within 60 days and the Council will complete a retrospective review to determine whether the research was biased and, if so provide a mitigation report if required by the relevant federal agency. The report will address the impact of the bias on a research project and the actions taken by or to be taken by the University to eliminate or mitigate the bias.

E. Reporting of Conflicts

The University must certify in each application for funding to which this policy applies, that it has a written and enforced administrative process to identify and manage financial conflicts of interests and that they will ensure compliance with all such related federal policies regarding FCOI.

The University must provide initial and ongoing FCOI reports to the federal agency, as required. Thus, the University is required to maintain records relating to all investigator disclosures of financial interests and its review of, and response to such disclosures (whether or not a disclosure resulted in Suffolk's determination of a FCOI) and all actions under the University's policy or retrospective review, if applicable, for at least three years from the date the final expenditures report is submitted to the federal agency, or as required by the specific agency. The University must also monitor investigator compliance with approved management plans throughout the duration of the funded project.

F. Public Disclosure

The University will make this policy available to the general public by posting it on the University's website under the ORSP heading.

Prior to the University's expenditure of any funds under a federally funded research project, it shall ensure public accessibility via its website of information concerning any significant financial interest disclosed to Suffolk that meets the following three criteria:

- The significant financial interest was disclosed and is still held by the Senior/Key Personnel as defined by federal policies
- The University determines that the significant financial interest is related to the federally funded research

- The University determines that the significant financial interest is a FCOI

The information that the University must make available via its website will include the following:

- Investigator's name
- Investigator's title and role with respect to the research project
- Name of the entity in which the significant financial interest is held
- Nature of the significant financial interest
- The approximate dollar value of the significant financial interest or a statement that the interest is one whose value cannot be readily determined by normal assessments of fair market value

This posted information must be updated at least annually and will remain accessible for at least three years from the date that the information was most recently updated.

G. Monitoring

The University may conduct random and for-cause monitoring of FCOI Management Plans.

H. Non-Compliance

Failure to comply with this policy or to follow an agreed upon Management Plan will result in a retrospective review and may result in the following actions:

- Termination of the Investigator's external funded project(s) at Suffolk
- Termination of Investigator's ability to submit proposals for external funding through Suffolk

Violations of this policy include, but are not limited to:

- Failure to comply with the disclosure process (by refusal to respond; by deliberately responding with incomplete, inaccurate, or misleading information, or otherwise)
- Failure to remedy significant conflicts of interest
- Failure to comply with a prescribed management plan

I. Additional Responsibilities

The University maintains this written Policy and will implement a process to identify and manage, reduce or eliminate these conflicts.

Suffolk shall, for any federal research funding from the PHS or any other federal funding agency that imposes FCOI requirements:

- Include in the sub award agreement terms that establish whether this policy or that of the sub recipient will apply to the sub recipient's Investigators and provide FCOI reports regarding sub recipient Investigators to the awarding federal funding agency
- Maintain records of, and related to, FCOI disclosures
- Report conflicting significant financial interest to the awarding component of the funding agency
- Inform the National Science Foundation, Office of the General Counsel if it is unable to satisfactorily manage a Significant Financial Conflict of Interest related to the project funded by NSF
- Report to the NIH the existence of any conflicting financial interests and assure that the interest has been managed, reduced, or eliminated in accordance with NIH regulations
- Maintain records related to Investigators disclosures of financial interests and the institution's review of, or response to such disclosures and all actions under this policy or retrospective review for at least three years from the date of the final expenditures report

Sources Referenced:

Office of Extramural Research. (2012, August 2). Financial Conflict of Interest. Retrieved August 2, 2012, from U.S. Department of Health and Human Services: <http://grants.nih.gov/grants/policy/coi/>

Suffolk University

Financial Conflict of Interest in Federally Funded Research Disclosure Statement

This Form must be completed by all investigators, including the principal investigator, co- investigators, and any other staff member who is responsible for the design, conduct or reporting of project activities. The form must be submitted at the time an application is routed for external federally funded research support. If project funding is secured, this disclosure must be completed annually. This form will be reviewed by the members of the Research Council. If financial conflict of interest is evident or questioned, the individual submitting this form will be asked to submit a plan to manage the conflict.

Name: _____ **Date:** _____

Email: _____

Department: _____ **Campus Phone:** _____

Role in Study: _____

Principle Investigator: _____

Title of Proposal: _____

Sponsor/ Awarding Agency: _____

This Financial Conflict of Interest in Federally Funded Research Disclosure Statement is to be completed in compliance with Suffolk University’s Financial Conflict of Interest in Federally Funded Research Policy. Please note, answering “yes” to any of the following questions does not mean the financial interest is inappropriate or improper, it may only that disclosure and evaluation, and in some cases, approval and oversight, are required. All thresholds listed below are an aggregate for the investigator, his or her spouse and dependent children. These questions apply to companies that could reasonably appear to be related to the proposed research.

1. Financial Interest in Publically Traded Companies

Over the past 12 months, have you received income or obtained other financial interest in excess of \$5000 from a publically traded company that is in any way related to or that might be affected by your proposed research activities? Examples of income include salary, consulting fees, honoraria, paid authorship, stock, stock options, or other ownership interests (based on public prices or other reasonable measures of fair market value). Excluded income includes salary, royalties, or other remuneration paid by Suffolk while a Suffolk employee; income from mutual funds not managed by the investigator, and income from lectures, workshops, panels etc. for universities and state, local, or federal agencies.

Yes No **If yes, entity name** _____

2. Financial Income from Non-Publically Traded Companies

Over the past 12 months, have you received income in excess of \$5000 from a non-publically traded company that is in any way related to or that might be affected by your proposed research activities? Examples of income include salary, consulting fees, honoraria, paid authorship.

Yes No If yes, entity name _____

3. Equity Interests in Non-publically Traded Companies

Over 12 months, have you held any equity interest in a non-publically traded company that is in any way related to or that might be affected by your proposed research activities?

Yes No If yes, entity name _____

4. Intellectual Property

Have you received income from intellectual property rights and interest (e.g. from patents, copyrights, or royalty agreements) from any companies in any way related to or that might be affected by your proposed research?

Yes No If yes, entity name _____

5. SBIR/STTR Phase II

Have you held any equity interest in a SBIR/STTR phase II funded company that is in any way related to or might be affected by your proposed research activities?

Yes No If yes, entity name _____

6. Paid Travel by Companies

Have you received any travel that has been paid for or reimbursed by any entity other than a Federal, state or local government, an institution of higher education, an academic teaching hospital, a medical center or a research institute associated with an institution of higher education?

Yes No If yes, please provide the following information. Please note that you may be asked for more specific information.

Purpose of the trip: _____

Destination: _____

Duration: _____

Who sponsored this travel: _____

If you have answered "yes" to any of the above questions, please work with the Director of the ORSP to develop a management plan to eliminate, reduce, or manage your FCOI.

Training:

By checking the box below, you are confirming that you completed the mandatory training on conflicts of interest via CITI (<https://www.citiprogram.org/>)

Yes No

Principal Investigator Only:

If you are the Principal Investigator, you are responsible for identifying all Investigators on the proposal and for informing these Investigators of their responsibilities to report Significant Financial Interests. An Investigator includes the project director and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research. An Investigator may include, for example, significant collaborators or consultants.

Please list here any individual that meets the definition for Investigator on this proposal.

Certification:

By executing below, I hereby certify:

- a. I have fully and to the best of my ability accurately completed this Disclosure Statement;
- b. I have reviewed and am in compliance with the Suffolk University's Policy on Financial Conflicts of Interest; and
- c. I will update this Disclosure Statement within thirty (30) days if, at any time, circumstances change such that the information provided in this Disclosure Statement is inaccurate or incomplete.
- d. If I am the Principal Investigator, I have identified above all individuals that currently meet the definition of Investigator and have informed those individuals of their responsibilities to complete this Disclosure Statement and the required training. I acknowledge that it is my responsibility to notify Suffolk University prior to allowing any new Investigator to commence research under this proposal, so that full compliance with this policy and regulation may be ensured.

Investigator Signature: _____ **Date:** _____

ORSP Director Signature: _____ **Date:** _____

Disclosure reviewed by the Research Council **Date:**