

UNIVERSIDADE DE SÃO PAULO

POLICY ON FINANCIAL CONFLICT OF INTEREST - UNIVERSITY OF SÃO PAULO

Considering the need of an institutional policy about financial conflicts of interest (FCOI) to allow that research projects to be awarded with resources from the Public Health Service (PHS) of the United States Department of Health and Human Services, which includes the National Institute of Health (NIH), University of São Paulo (USP) established its Policy on Conflicts of Financial Interest for research funded by the US PHS.

Introduction

A conflict of interest may exist if circumstances reasonably create a risk that your professional judgement or decision making may be unduly influenced by other interests outside of University activities. It doesn't mean that there will actually be such an influence, but whether there is potential for this or if it could reasonably be perceived that way.

Public Health Service/National Institutes of Health (PHS/NIH) seeks to promote objectivity in research through its FCOI (Financial Conflict of Interest) policy in accordance with US law (42 CFR Part 50- Subpart F - [insert link](#)) to ensure that the design, conduction and reporting of the results of research funded by the PHS / NIH are free from financial conflicts of interest.

All organisations in receipt of NIH funding required to demonstrate compliance with the NIH Financial Conflict of Interest Policy. It's required that organizations identify, disclose and manage the FCOI of grant recipients when it is identified that a researcher has a 'Significant Financial Interest' (SFI) that could affect the objectivity of funded research. To meet this requirement, researchers must declare their Significant Financial Interests (SFI). In addition, regular and mandatory FCOI training is required to all researchers as well as disclosure and management of identified FCOIs.

This policy applies to all research activities supported by a PHS/NIH funding, through direct funding or through a cooperative agreement (sub-awardee).

Responsibilities

A. Researchers

1. To disclose any Significant Financial Interest (SFI) within the timeframes specified by the sponsor.

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2. To complete the compulsory FCOI online training. The researcher must complete NIH online FCOI tutorial prior to undertaking any PHS/NIH funded research and at least every four years.
3. To adhere to the agreed Management Plan in case of any identified FCOI.
4. Principal Investigator must ensure all staff working on the project adhere to the FCOI policy and must ensure they also complete the compulsory NIH online FCOI training. The PI must also inform new researchers of the requirements when working on projects funded by NIH.

B. University

1. review disclosures of SFI and determine if the SFI constitutes a FCOI.
2. Manage FCOIs and, if necessary, put a management plan in place to manage any potential conflict of interest and compliance monitoring under institutional supervision.
3. Submit initial and annual FCOI reports to PHS / NIH
4. Maintain records relating to all investigators SFI disclosures and all actions taken relating to such disclosures for at least three years from the date of the final report is submitted to the NIH or, where applicable, from other dates specified in NIH policy.
5. Take relevant corrective actions.
6. Receive, review and report changes of FCOIs.
7. Develop and implement processes at institutional level to comply with PHS / NIH policy.
8. Report any changes of FCOIs to NIH.

Training Requirements

All investigators must understand their responsibilities regarding the PHS/NIH FCOI policy and must complete the NIH online tutorial available at <http://grants.nih.gov/grants/policy/coi/tutorial2011/fcoi.htm>

1. prior to engaging in PHS/NIH-Funded Research
2. at least once every 4 years; and
3. immediately when any of the following circumstances apply:

- (i) this supplemental guidance or procedures relating to FCOI policies are revised in any manner that affects the requirements of Investigators;
- (ii) An Investigator is new to the University, even if the PHS/NIH Funded Research has already begun; or
- (iii) An Investigator is not in compliance with this policy or with the management plan.

When the NIH on-line tutorial has been completed, the Investigator must save an electronic copy of the certificate generated through the system and provide a copy to the Research Provost's Office (PRP).

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Definition of Significant Financial Interest (SFI)

A financial interest consisting of one or more of the following interests of the Investigator (and those of the Investigator's spouse and dependent children) that reasonably appears to be related to the Investigator's institutional responsibilities:

1. With regard to any 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 and the value of any equity interest in the entity as of the date of disclosure, when aggregated, exceeds US\$5,000. 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 measures of fair market value;
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, when aggregated, exceeds US\$5,000, or when the Investigator (or the Investigator's spouse or dependent children) holds any equity interest (e.g., stock, stock option, or other ownership interest); and
3. Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.

The term SFI does not include the following types of financial interests:

1. salary, royalties, or other remuneration paid by the University to the Investigator if the Investigator is currently employed or otherwise appointed by the University, including intellectual property rights assigned to the University and agreements to share in royalties related to such rights;
2. 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;
3. income from seminars, lectures, or teaching engagements 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 centre, or a research institute that is affiliated with an institution of higher education; or
4. income from 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 centre, or a research institute that is affiliated with an institution of higher education.

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Determination of FCOIs

Research Provost's Office determines, on behalf of the University, whether an FCOI exists for the purposes of the NIH policy, and whether the significant financial interest declared by the Investigator may reasonably be said to be related to the PHS/NIH research by assessing whether the SFI:

1. could be affected by the PHS/NIH research; or
2. is in an entity whose financial interest could be affected by the PHS/NIH research.

If the SFI is determined to be related to the PHS/NIH research, the Research Provost's Office must determine whether the SFI could directly and significantly affect the design, conduct, or reporting of the PHS/NIH research.

If the Significant Financial Interest is determined to relate to the NIH research and affect the design, conduct or reporting of the PHS/NIH research, it is an FCOI, and must be managed.

Research Provost's Office may involve the Investigator in the determination of whether a significant financial interest is related to the PHS/NIH research, but the determination of whether an FCOI exists must be made by Research Provost's Office.

Management Plans

The Research Provost's Office must review all SFIs disclosed by investigators to determine whether they are related to PHS/NIH funded research and, if so, whether they constitute a Conflict of Financial Interest.

If an SFI is determined to be an FCOI, the Research Provost's Office will set out a plan to manage, reduce or eliminate the conflict.

Management plans may include the following actions:

- Public disclosure of financial conflicts of interest (e.g., when presenting or publishing the research);
- For research projects involving human subjects research, disclosure of financial conflicts of interest 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 financial conflict of interest;
- Modification of the research plan;
- Change of 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); or
- Severance of relationships that create financial conflicts.

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The management plan shall also include the following details:

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

Reporting

Unless the conflict is eliminable, the plan must be submitted to the PHS funder; in the case of the NIH this will be via the electronic Research Administration (eRA) Commons FCOI Module. Research Provost's Office is responsible for ensuring that reports are submitted on time as and when required.

Updated or annual FCOI reports must include the status of the management plan (i.e. whether the financial conflict is still being managed or an explanation of why the financial conflict no longer exists) and a description of any changes to the management plan since the last FCOI report was submitted.

Reports must be submitted prior to any expenditure of funds under a PHS-funded project. Note that reports need only be made if the Head of Department determines that an SFI constitutes an FCOI. But reports must also be submitted if an Investigator does not disclose an SFI in the timeframe required or the University does not review a disclosure but later determines that an FCOI exists.

For new Investigators who join the project, the SFI must be disclosed within 60 days. For any FCOI previously reported, the University must provide an annual FCOI report to address the status of the financial interest and any changes to the management plan. The plan must specify whether the FCOI is still being managed or explain why the FCOI no longer exists.

All FCOI reports must include sufficient information to enable the PHS-funder to understand the nature and extent of the FCOI and to assess the appropriateness of the management plan. The reports include (but are not limited to):

- Project number;
- Name of the PI;

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- Name of the Investigator with the Financial Conflict of Interest;
- Name of the entity with which the Investigator has a Financial Conflict of Interest;
- Nature of the financial interest (e.g., equity, consulting fee, travel reimbursement, honorarium);
- Value of the financial interest (dollar ranges are permissible: \$0-\$4,999; \$5,000- \$9,999; \$10,000- \$19,999; amounts between \$20,000-\$100,000 by increments of \$20,000; amounts above \$100,000 by increments of \$50,000), or a statement that the interest is one whose value cannot be readily determined through reference to public prices or other reasonable measures of fair market value;
- A description of how the financial interest relates to the NIH-funded research and why the Institution determined that the financial interest conflicts with such research.

Requirements regarding subrecipients

If the University of São Paulo is the prime awardee, the University delegates responsibility for compliance with the NIH FCOI policy relating to identification, disclosure, determination and management of FCOIs to each sub-awardee, and will specify in any sub-awardee agreement all matters necessary to implement 42 CFR 50.604, including that the subawardee must:

1. comply with the requirements of the NIH FCOI policy;
2. submit all requisite details of FCOIs to the University of São Paulo:
 - (i) prior to the expenditure of funds; and
 - (ii) within 60 days of any subsequently identified FCOI.
3. promptly notify the University of any management plan and suspected non-compliance; and
4. provide a declaration that all FCOIs have been identified, disclosed and managed in accordance with NIH requirements

Failure to comply

If an Investigator fails to comply with the policy or a management plan subsequently put in place, the University must, within 120 days, undertake a retrospective review of the research project to determine if there is any bias in the design, conduct or reporting of the research. If a bias is found, the PHS funder must be notified and provided with a mitigation plan and thereafter report annually as normal, unless the University decides further interim measures are necessary. The funder is entitled to suspend or terminate the award.