

University of San Francisco
Office of Sponsored Programs
Policy and Procedures on Financial Conflict of Interest in
Research

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I. Policy Statement

The University of San Francisco (USF) recognizes the importance of promoting objectivity in research that is sponsored by federal funding. USF has established this policy regarding significant financial conflicts of interest (FCOI) for sponsored research to ensure that its research is free from bias and the appearance of bias. USF and its investigators will be responsible for managing and eliminating any actual or prospective conflicts of interest that may occur.

Rules promulgated by the Public Health Service of the United States Department of Health and Human Services (HHS) also require that investigators disclose reimbursed or sponsored travel relating to their institutional responsibilities. Travel that is reimbursed or sponsored by federal, state, or local government agencies, institutions of higher education, academic teaching hospitals, medical centers, or research institutes affiliated with institutions of higher education, is not required to be disclosed.

This policy reflects the requirements of the following agencies:

PHS, including the National Institutes of Health (NIH), Agency for Health Research and Quality, the Health Resources and Services Administration and other PHS agencies.

- 42 CFR Part 50 Subpart F (grants and cooperative agreements) 42 CFR 50, Subpart F, "Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is Sought".
- 45 CFR Part 94 (contracts) Initial Regulation effective 10-1-95
<http://www.gpo.gov/fdsys/pkg/CFR-2007-title45-vol1/pdf/CFR-2007-title45-vol1-sec94-4.pdf>
- Revised Final Rule published on 8/25/11 and effective August 2012
http://grants.nih.gov/grants/policy/coi/fcoi_final_rule.pdf

Any other relevant state, federal regulations or sponsor disclosure requirements applicable to the research but not listed above.

II. Definition of Financial Conflict of Interest

Financial Interest means anything of monetary value, whether or not the value is readily ascertainable. Note that the monetary threshold for which significant FCOI requires disclosures for several federal agencies is \$5,000 when aggregated over a twelve-month period.

Significant Financial Conflict of Interest (FCOI) means a significant financial interest that could directly and significantly impact the design, conduct and reporting of the Research.

The term Significant Financial Interest does not include:

- salary, royalties or other remuneration paid by the University to the Investigator if the Investigator is currently employed or otherwise appointed by USF, including intellectual property rights assigned to USF and agreements to share in royalties related to such rights;
- income from service on advisory committees or review panels for public or nonprofit entities;

- royalties or other payments from publicly traded entities, when aggregated for the Investigator, Investigator's spouse, and the Investigator's dependent children, are not expected to exceed \$5,000 during the previous twelve-month period;
- income from self-authored textbooks, software, etc. that are used for your teaching purposes;
- travel that is reimbursed by a federal, state, or local government agency, or an institution of higher education as defined at 20 U.S.C. 1001(a), or a research institute that is affiliated with an institution of higher education;
- income from investment vehicles, such as mutual funds and retirement accounts, as long as the Investigator does not directly control decisions made in these investment vehicles;
- income from seminars, lectures, or teaching engagements sponsored by or derived from service on an advisory or review panel for a federal, state, or local government agency, institution of higher education, or a research institute that is affiliated with an institution of higher education.

A *Significant Financial Interest* becomes a *Financial Conflict of Interest* if it could result in personal gain, advantage to others to the detriment of USF, or influence the design, conduct and reporting of the Investigator's Research.

III. Definitions of Terms in the Policy

Research means a systematic investigation, study or experiment designed to develop or contribute to generalizable knowledge relating broadly to public health, including behavioral and social-science research. The term encompasses basic and applied research (e.g., a published article, book or book chapter) and product development (e.g., a diagnostic test or drug). It includes any activity for which research funding is available from NIH or any other PHS component. The funding may be a cooperative agreement, a research grant, a career development award, a center grant, an individual fellowship award, an infrastructure award, an institutional training grant, program project, or research resources award.

Investigator is the project director or principal investigator and any other person, regardless of title or position, who is responsible for the design, conduct or reporting of funded research.

Senior/Key Personnel means the Project Director and any other person identified as senior/key personnel by USF in the grant application, progress report, or any other report submitted to the PHS by USF.

Project Director/Principal Investigator means the director or principal investigator of a PHS-funded research project; the PID/PI is included in the definitions of senior/key personnel and investigator.

Institutional Responsibilities are an investigator's professional responsibilities on behalf of USF. These could include teaching, community service, research, and participation on university committees.

Institutional Official is the designated person responsible for soliciting and reviewing disclosures of significant FCOI. The Institutional Official for USF is the Senior Vice Provost for Academic Affairs.

IV. Investigator Responsibilities

The responsibilities of the Principal Investigator are to:

- Disclose to USF any significant financial interest (and those of the PI's spouse and dependent children) related to the grant award a) at the time of the award, b) at least annually during the period of award, and c) within 30 days of acquiring a new significant financial interest. Completion of the Significant Financial Interest Disclosure Form required.
- Disclose any changes to the information provided in significant financial conflict of interest form within 30 days of the change. Examples of changes that need to be reported are listed below:
 - Creation of a new company
 - Sponsorship of research by an outside entity
 - Change in personal financial remuneration received from outside entities
 - Change to unremunerated service role (i.e., serving on a board of a non-profit cooperation)
 - Reimbursement for sponsored travel
 - Addition of new investigators
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- Completing all required training, disclosing Financial Interests relating to Research, for mitigating risks associated with Significant Financial Interests, and for assisting with the management of any identified FCOI. This includes completing Financial Conflict of Interest training immediately for Investigators with current NIH or NSF grants awarded after August 2012. This pertains to Investigators whose current grants were modified after this date. The mandatory training must occur prior to engaging in research and every 4 years following the initial training. The FCOI modules can be accessed at:
https://grants.nih.gov/grants/policy/coi/tutorial2018/story_html5.html
- Ensure that students, collaborators and sub-awardees submit required disclosures and complete training as required by the relevant regulation.
- Comply with USF's policy and procedures.
- Ensure compliance with all applicable laws and regulations relating to USF's responsibilities, including certification of compliance, maintenance of records, responses to requests for information, and reporting requirements.

V. Institutional Responsibilities

- Develop and implement policies and procedures that promote compliance with regulations
- Provide information to Investigators regarding the appropriate regulations, the University policy, the Investigator's role in the process and access to the relevant training. Ensure that the USF Financial Conflict of Interest policy is available on the OCG webpage.
- Appoint an Institutional Official to review disclosures of Significant FCOI from all investigators. Evaluate significant financial interests and determine any that may qualify as an FCOI.
- Meet with the Principal Investigator, if requested, to discuss the Significant Financial Interest disclosure. If there is a finding of FCOI, the Institutional Official will help the Principal Investigator to effectively manage, reduce, or eliminate the conflict.

- Gather information and supporting documentation from the Principal Investigator, if a Significant Financial Interest is disclosed. The Institutional Official will work collaboratively with the investigator to develop a management plan, if required, and make the plan available to the agency.
- Maintain records of financial disclosures and actions taken to resolve actual or potential Financial Conflicts of Interests for 3 years after the later of the termination of the PHS or National Science Foundation (NSF) [DEFINE THESE TERMS] contract, completion of the research to which such contracts relate, or the resolution of any government action involving these records.
- Provide annual FCOI reports to the appropriate agency if an FCOI exists. The report will include the status of the FCOI and how it is being managed or an explanation of why it no longer exists.
- Ensure that all proposed recipients of subawards under a PHS and/or NSF sponsored award comply with the FCOI policy. If the subrecipient does not have a publicly posted FCOI policy, they will be required to comply with USF's policy. Subrecipients are required to report FCOI to USF within 45 days of discovery; USF's Institutional Official will reporting it to the agency on behalf of the subrecipient.

VI. Management of FCOI/COI:

- FCOI must be evaluated and a determination made prior to the beginning of sponsored research.
- If FCOI is determined, a plan must be put in place to manage the FCOI.

VII. Enforcement of the Policy:

- The University reserves the right to deny any vendor, bid, purchase, service request, or any other procurement described within this policy for any reason.
- All procurement activity must adhere to all federal, local, and state laws, federally regulated Uniform Guidance, specific sponsored project and contract guidelines, and USF's policies.
- Any department, program or individual who does not adhere to the policy enclosed will be subject to a review based on USF policies and possible suspension of research until an investigation can be completed. If the PI/PD has not adhered to the conflict of interest or financial conflict of interest policy then a retrospective review must be completed within 120 days of learning of the noncompliance.
 - Depending on the outcome of the review, the Office of Academic Affairs will determine the steps to follow including the development of a management plan.
- The Principal Investigator and USF's responsibility is further extended to all sub-recipients of externally funded Sponsored Projects for monitoring and adherence to the University's policy. <https://grants.nih.gov/grants/policy/coi/index.htm>



UNIVERSITY OF
SAN FRANCISCO

Financial Interest Disclosure Form

Investigator Name _____ Department _____

Proposal Title _____

Sponsor _____ Date _____

Please complete this form and note that failure to disclose a Financial Conflict of Interest can result in forfeiture of the award or may be subject to disciplinary action.

I confirm that I have read the Financial Conflict of Interest Policy and that the information is true to the best of my knowledge.

I agree to:

- 1) Update this disclosure, if awarded, either on an annual basis or, as applicable, within (30) days as a new Significant Financial Interest occurs.
- 2) Comply with any conditions or restrictions imposed by the University to manage, reduce, or eliminate actual or potential conflicts of interest or forfeit the award.

Complete this section below:

I am disclosing the following Significant Financial Interest (SFI) (check all that apply) that are related to my institutional responsibilities. Please use page 2 to explain and identify the business enterprise or entity involved, the nature of the relationship, and amount of the interest.

- Salary or other payment of services (e.g., consulting fees or honoraria)
- Equity interests or any remuneration (e.g., stocks, stock options, other ownership interests, including non-publicly traded entities)
- Intellectual property rights (e.g., patents, copyrights, and royalties from such rights)
- Travel (reimbursed or sponsored) related to institutional responsibilities
- I do not have a Significant Financial Interest (SFI) to disclose.

Investigator's Name _____

Investigator's Signature _____ Date _____

Dean's Signature _____ Date _____

(Only required if FCOI exists)

Please complete and submit this signed form as confidential mail to the Office of Sponsored Programs, Masonic East Building, Room 119, USF.

Administrative Review and Approval

Significant Financial Interest Review

Based on the activity reported and to the best of my knowledge and in my judgment:

- No SFI in conflict with this submission exists.
- A conflict of interest may exist, but does not appear to be significant.
- A SFI that warrants further review may exist, we will contact you for further information and a conflict-of-interest management plan will be devised as necessary.

Approver's Signature

Date

Please provide a complete description of all related details. In disclosing your significant financial interest, please include the business enterprise or entity involved, the nature of the relationship, and amount of interest.