



**Policy on Academic Financial Conflict of Interest in Research
Public Health Service and National Science Foundation
Grants and Cooperative Agreements**

Approved by: Smith College Senior Administrators (August 15, 2012)

Effective Date: August 24, 2012

Related Policies: **Smith College Conflict of Interest Policy – Staff Handbook**

http://www.smith.edu/hr/handbook_section1.php

Office/Administrator Responsible: Office of Sponsored Research, Director of Sponsored Research

INTRODUCTION

The 2011 revised regulation, *Responsibility of Applicants for Promoting Objectivity in Research for which Public Health Service Funding is Sought*, seeks to promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct, and reporting of research performed under Public Health Service (PHS) grants (e.g., NIH and FDA grants) or cooperative agreements will be free from bias resulting from investigator financial conflicts of interest. This regulation is commonly referred to as the Financial Conflict of Interest (FCOI) regulation.

(http://grants.nih.gov/grants/policy/coi/fcoi_final_rule.pdf). **Smith College also applies this policy to National Science Foundation (NSF) Grants and Cooperative Agreements.**

The policy that follows defines significant financial interests and the disclosure of such interests. These are interests that could directly affect the design, conduct, or reporting of research. Smith College will review disclosures to determine if financial interests may create an actual or potential financial conflict of interest with the project and the institutional responsibilities of the investigator(s). Federal regulations require that financial conflicts of interest are appropriately reported and managed.

Per the regulation, an Institution applying for or receiving PHS or NSF funding from a grant or cooperative agreement must be in compliance with all of the revised regulatory requirements no later than August 24, 2012, and immediately upon making the Institution's Financial Conflict of Interest policy publicly accessible as described in 42 CFR part 50.604(a).

This policy is intended to signify that Smith College, in applying for or receiving PHS or NSF funding from a grant or cooperative agreement that is covered by the 2011 revised regulation, is in full compliance with all the regulatory requirements.

SCOPE

The regulation and this Policy apply to research (defined at the end of this policy) and include any activity for which research funding is available from PHS or NSF through a grant or cooperative agreement. The regulation and this Policy explicitly apply to research authorized under the regulation, such as a research grant, career development grant, center grant, individual fellowship award, infrastructure award, institutional training grant, program project, conference and workshop grant, and research resources award.

PHS and NSF award programs that are excluded from the regulation and this Policy are the Small Business Innovative Research (SBIR) and Small Business Technology Transfer Research (STTR) Phase I applications.

The regulation and this Policy are applicable to **awardees, subrecipients, subgrantees and collaborators (e.g., subcontractors or consortium members)**. The 2011 revised regulation is applicable to each Institution that applies for or receives PHS or NSF funding for research through grants or cooperative agreements and, through the implementation of the regulation by each Institution, to each Investigator planning to participate in, or participating in, such research. A subrecipient relationship is established when federal funds flow down from or through an awardee Institution to another individual or entity and the subrecipient will be conducting a substantive portion of the PHS or NSF-funded research project and is accountable to the awardee institution for programmatic outcomes and compliance matters. Accordingly, as a recipient of federal funds from an awardee Institution, the Financial Conflict of Interest regulation applies to subrecipients (e.g., subcontractors or consortium members). See 42 CFR 50.604 (c).

WHO NEEDS TO KNOW THIS POLICY

All staff who provide support to the college and its faculty on sponsored research and all faculty, staff, and/or all Investigators who may apply for, receive, plan to participate in or who are participating in such research as is conducted under PHS or NSF grants or other awards covered by this policy are responsible to know this policy and comply with its requirements.

POLICY

Smith College will fully comply with the Federal Rule titled *Responsibility of Applicants for Promoting Objectivity in Research* as posted in the Federal Register / Vol. 76, No. 165 / Thursday, August 25, 2011 / Rules and Regulations §42 CFR Part 50 and the requirements of the National Science Foundation as respects all grants or awards for which Public Health Service or NSF Funding is sought or received. The requirements of the policy and the management of the processes that are necessary under this regulation are delineated in the following **Procedures** which are incorporated by reference into this policy.

PROCEDURES

1) INVESTIGATOR REQUIRED TO REPORT CONFLICTS OF FINANCIAL INTEREST

The regulations require the institution to:

(a) Require that each Investigator who is planning to participate in the PHS or NSF funded research disclose to the Office of Sponsored Research the Investigator's significant financial interests (and those of the Investigator's spouse and dependent children) no later than the time of application for PHS or NSF funded research.

(b) Require each Investigator who is participating in the PHS or NSF funded research to submit an updated disclosure of significant financial interests at least annually, in accordance with the specific time period prescribed by the Institution, during the period of the award.

(i) Such disclosure shall include any information that was not disclosed initially to the Institution or in a subsequent disclosure of significant financial interests (e.g., any financial conflict of interest identified on a PHS or NSF funded project that was transferred from another Institution), and shall include updated information regarding any previously disclosed significant financial interest (e.g., the updated value of a previously disclosed equity interest).

(c) Require each Investigator who is participating in the PHS or NSF funded research to submit an updated disclosure of significant financial interests within thirty days of discovering or acquiring (e.g., through purchase, marriage, or inheritance) a new significant financial interest.

INVESTIGATOR RESPONSIBILITIES

As a condition of applying for PHS or NSF funded grants, awards or other funds subject to the regulations outlined in this Policy, Investigators are responsible for and required to

- 1) Complete college provided or other required training on the regulations and their obligations under the regulations (**training only applies to PHS funded grants or cooperative agreements**);
- 2) Report all Financial Conflicts of Interest in accordance with the procedures set forth by the Office of Sponsored Research;
- 3) Participate in and comply with any college FCOI Management Plan, including any retrospective review and/or mitigation plan; and
- 4) Support the Office of Sponsored Research with any FCOI as appropriate with any sub-recipients or sub-awardees if the Investigator is the Primary Investigator.

What financial interests are covered by the regulation and what is a Significant Financial Interest?

The regulation covers all financial interests that have monetary value, whether or not the value is readily ascertainable.

The 2011 revised regulation defines a "Significant Financial Interest" as follows:

- 1) 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:
 - i) 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 \$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;
- ii) 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 \$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); or
 - iii) Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.
- 2) Investigators also must disclose 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; this includes reimbursed or sponsored travel by a private for-profit or non-profit but does **not** apply to Travel that is reimbursed or sponsored by a federal, state, or local government agency, a U.S. 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.
- Disclosure shall be on a form provided by the Office of Sponsored Research which will include, at a minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration of the travel. In accordance with the college's FCOI policy, the Director of Sponsored Research 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 PHS or NSF funded research.
- 3) The term *significant financial interest* does **not** include the following types of financial interests:
- i) salary, royalties, or other remuneration paid by the Institution to the Investigator if the Investigator is currently employed or otherwise appointed by the College, including intellectual property rights assigned to the College and agreements to share in royalties related to such rights;
 - ii) 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;
 - iii) income from seminars, lectures, or teaching engagements sponsored by a federal, state, or local government agency, a U.S. 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; and
 - iv) or income from service on advisory committees or review panels for a federal, state, or local government agency, a U.S. 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.

These financial interests are not included in the definition of significant financial interest regardless of total dollar amount (the threshold is not applicable due to the source of funding).

INSTITUTIONAL RESPONSIBILITIES

2) Training — Applicable to PHS-funded grants or cooperative agreements

The Office of Sponsored Research shall

- (a) Inform each Investigator of the Institution's policy on financial conflicts of interest;

- (b) Inform each Investigator of the Investigator's responsibilities regarding disclosure of significant financial interests and of these regulations; and
- (c) Require each Investigator to complete training regarding the same prior to engaging in research related to any PHS-funded grant and at least every four years, and immediately when any of the following circumstances apply:
 - (i) The Institution revises its financial conflict of interest policies or procedures in any manner that affects the requirements of Investigators
 - (ii) An Investigator is new to an Institution; or
 - (iii) An Institution finds that an Investigator is not in compliance with the Institution's financial conflict of interest policy or management plan.

3) **Additional Responsibilities of the Office of Sponsored Research**

- a) The Director of Sponsored Research will solicit and review disclosures of significant financial interests from each Investigator who is planning to participate in, or is participating in, the PHS or NSF funded research.
- b) The Office of Sponsored Research will maintain guidelines to determine whether an Investigator's significant financial interest is related to PHS or NSF funded research and, if so related, whether the significant financial interest is a financial conflict of interest.
 - i) An Investigator's significant financial interest is related to PHS or NSF funded research when the Institution, through its designated official(s), reasonably determines that the significant financial interest could be affected by the PHS or NSF funded research; or
 - ii) The PHS or NSF funded research is in an entity whose financial interest could be affected by the research. The college may involve the Investigator in the determination of whether a significant financial interest is related to the research.
 - iii) A financial conflict of interest exists when the college, through its designated official(s), reasonably determines that the significant financial interest could directly and significantly affect the design, conduct, or reporting of the PHS or NSF funded research.
- c) The Office of Sponsored Research, with assistance from the Finance Office, will manage all financial conflicts of interest, (including any financial conflicts of a subrecipient Investigator) in accordance with §50.605 (a) including
 - (i) Develop and implement a management plan and, if necessary, a retrospective review and mitigation report; and
 - (ii) Maintain records relating to all Investigator disclosures of financial interests and the Institution's review of, and response to, such disclosures (whether or not a disclosure resulted in the Institution's determination of a financial conflict of interest) and all actions under the Institution's policy or retrospective review, if applicable, for at least three years from the date the final expenditures report is submitted to the PHS or NSF or, where applicable, from other dates specified in 45 CFR 74.53(b) and 92.42 (b) for different situations.
- d) The Office of Sponsored Research and the Office of the Provost has established enforcement mechanisms and provides for employee sanctions or other administrative actions to ensure Investigator compliance as appropriate to each specific circumstance. Enforcement mechanisms may include follow-up for information, withdrawal of funding or disciplinary action up to an including termination.

- 4) The Office of Sponsored Research shall provide initial and ongoing FCOI reports to the PHS and NSF as required pursuant to § 50.605(b)
- 5) **Use of Sub-recipients** — If any part of the PHS or NSF funded research is conducted through a subrecipient (e.g., subcontractors or consortium members), the Office of Sponsored Research, with the support of the Primary Investigator (i.e., awardee Institution), will take reasonable steps to ensure that any subrecipient Investigator complies with this subpart by

(a) Incorporating as part of a written agreement (contract) with the subrecipient terms that establish whether the financial conflicts of interest policy of the awardee Institution or that of the subrecipient will apply to the subrecipient's Investigators.

(i) If the subrecipient's Investigators must comply with the subrecipient's financial conflicts of interest policy, the subrecipient shall certify as part of the agreement referenced above that its policy complies with this subpart. If the subrecipient cannot provide such certification, the agreement shall state that subrecipient Investigators are subject to the financial conflicts of interest policy of the awardee Institution for disclosing significant financial interests that are directly related to the subrecipient's work for the awardee Institution;

(ii) Additionally, if the subrecipient's Investigators must comply with the subrecipient's financial conflicts of interest policy, the agreement referenced above shall specify time period(s) for the subrecipient to report all identified financial conflicts of interest to the awardee Institution. Such time period(s) shall be sufficient to enable the awardee Institution to provide timely FCOI reports, as necessary, to the PHS as required by this subpart;

(iii) Alternatively, if the subrecipient's Investigators must comply with the awardee Institution's financial conflicts of interest policy, the agreement referenced above shall specify time period(s) for the subrecipient to submit all Investigator disclosures of significant financial interests to the awardee Institution. Such time period(s) shall be sufficient to enable the awardee Institution to comply timely with its review, management, and reporting obligations under this subpart.

(b) Providing FCOI reports to the PHS or NSF Awarding Component regarding all financial conflicts of interest of all subrecipient Investigators consistent with this subpart, i.e., prior to the expenditure of funds and within 60 days of any subsequently identified FCOI.

DEFINITIONS

“Entity” as used in the Financial Conflict of Interest regulation

Entity means any domestic or foreign, public or private, organization (excluding a Federal agency) from which an Investigator (and spouse and dependent children) receives remuneration or in which any person has an ownership or equity interest.

“Financial Conflict of Interest”

A *Financial Conflict of Interest* exists when the Institution, through its designated official(s), reasonably determines that an Investigator's Significant Financial Interest is related to a PHS-funded research project and could directly and significantly affect the design, conduct or reporting of the research.

“Institution” for purposes of the Financial Conflict of Interest regulation

Institution means any domestic or foreign, public or private, entity or organization (excluding a Federal agency) that is applying for or that receives PHS or NSF research funding.

“Institutional responsibilities”

“Institutional responsibilities” are defined by the 2011 revised regulation as an Investigator’s professional responsibilities on behalf of the Institution, and as defined by the Institution in its policy on Financial Conflict of Interest. It includes such activities as research, research consultation, teaching, professional practice, Institutional committee memberships, and service on panels such as Institutional Review Boards or Data and Safety Monitoring Boards.

“Investigator”

For the purpose of this policy “Investigator” means 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 research funded by the PHS or NSF, or proposed for such funding, which may include, for example, collaborators or consultants. It does *not* restrict “investigator” to the PI – Principal Investigator. Institutions should consider the role, rather than the title, of those involved in research and the degree of independence with which those individuals work. When the definition of investigator is limited to titles or designations (e.g., to principal investigators, key personnel, faculty) the risk is that an unidentified FCOI may comprise the research enterprise.

In addition, the Investigator’s spouse and dependent children have been eliminated from the definition of “Investigator” under the 2011 revised regulation; however, they are referenced in the definition of “Significant Financial Interest” because the Investigator must also disclose Significant Financial Interests of his/her spouse and dependent children. (see definition of Significant Financial Interest).

“Public Health Service”

PHS means the Public Health Service of the U.S. Department of Health and Human Services, and any components of the PHS to which the authority involved may be delegated. PHS granting agencies include (but are not limited to): Administration for Children and Families (ACF), Agency for Healthcare Research and Quality (AHRQ), Centers for Disease Control and Prevention (CDC), Department of Health and Human Service (DHHS/OS), Food and Drug Administration (FDA), Health Resources and Services Administration (HRSA), the National Institutes of Health (NIH) and Substance Abuse and Mental Health Services Administration (SAMHSA) (see www.globalhealth.gov for a complete list of all HHS Operating Divisions).

“Research”

The definition of the term *Research* provides a non-exhaustive list of examples of the different types of PHS-funding mechanisms to which the regulation applies such as a research grant, career development award, center grant, individual fellowship award, infrastructure award, Institutional training grant, program project, or research resources award. The regulation defines “Research” as any such activity (described at 42 CFR 50.603) for which research funding is available from a PHS or NSF Awarding Component through a grant or cooperative agreement.

“Senior/Key Personnel”

As referenced in the 2011 revised regulation, “Senior/Key Personnel” in funded research means the Project Director/Principal Investigator (PD/PI) and any other person *identified* as senior/key personnel by the Institution in the grant application, progress report, or any other report submitted to the PHS or NSF funded agency by the Institution under the regulation.