Purpose:

The 2011 revised regulation, Responsibility of Applicants for Promoting Objectivity in Research for which Public Health Service Funding is Sought, 42 CFR.50.601 et seq., 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 Services (PHS) grants or cooperative agreements will be free from bias resulting from an investigator’s financial conflicts of interest. The National Science Foundation (NSF) has also issued a Policy on Financial Conflict of Interest in its Award and Administration Guide at Chapter IV.A. containing parallel requirements.

This policy is intended to establish requirements to ensure that the College of the Holy Cross is in full compliance with all pertinent regulatory requirements in applying for or receiving PHS or NSF funding from a grant or cooperative agreement and is applicable to any PHS or NSF proposals submitted and/or awards received on or after August 24, 2012.

Scope

This Policy applies to research and includes any activity for which research funding is available from PHS or NSF through a grant or cooperative agreement. This Policy applies to research authorized under the PHS Act or by the NSF or other statutory authority, such as a research grant, career development grant, center grant, individual fellowship award, infrastructure award, institutional training grant, program project, conference and workshop grant, or research resources award.

PHS award programs that are excluded from this Policy are the Small Business Innovative Research (SBIR) and Small Business Technology Transfer Research (SITR) Phase I applications.
This Policy is applicable to awardees, subrecipients, subgrantees and collaborators (e.g., subcontractors or consortium members). The 2011 revised regulations issued by PHS and NSF are 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 sub recipient relationship is established when federal funds flow down from or through an awardee Institution to another individual or entity and the sub recipient will be conducting a substantive portion of the 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, this Financial Conflict of Interest Policy applies to sub recipients (e.g., subcontractors or consortium members). See 42 CFR 50.604(c), 50 CFR 510.

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 to comply with its requirements.

Policy:

The 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 as respects all grants or awards for which Public Health Service Funding is sought or received. The College will also comply with the requirements of the Conflict of Interest Policy of the National Science Foundation (NSF) as set forth in Chapter IVA of the NSF Award and Administration Guide. The requirements of the foregoing policies and the management of the processes that are necessary to do so are set forth in the following Procedures which are incorporated by reference into this policy.

Procedures:

1) Investigator Required to Report Conflicts of Financial Interest

The College will:

(a) require that each Investigator who is planning to participate in the PHS or NSF-funded research disclose to the Director of Corporate and Foundation Grants and Corporate Giving (“the Director”) 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.
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 30 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) attend College provided or other required training on the regulations and their obligations under the regulations
2) report all Financial Conflicts of Interest to the Director in accordance with the procedures set forth by the Office of the Dean of the College.
3) participate in and comply with any College Financial Conflict of Interest Management Plan including any retrospective review and/or mitigation plan.
4) advise the Director of any Financial Conflict of Interest 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.

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:
   (a) 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 a PHS funded project or $10,000 for a NSF funded project. 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;
   (b) 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 for a PHS funded project or $10,000 for a NSF funded project, 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
(c) Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.
(d) Investigators must disclose the occurrence of any reimbursed or sponsored travel related to their institutional responsibilities, including payments made on behalf of the investigator and reimbursed or sponsored travel by a private for-profit or non-profit agency. The investigator is responsible for identifying these transactions, even if an exact monetary value is not readily available.
(e) Investigators do not need to report: 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.
(f) Disclosure shall include: the purpose of the trip; the identity of the sponsor/organizer; the destination; and the duration of the travel. In accordance with this policy, the Director will determine if further information is needed, including a determination or disclosure of monetary value, in order to determine whether the travel constitutes a Financial Conflict of Interest with the PHS or NSF-funded research.

2) The term significant financial interest does not include the following types of financial interests:
(a) 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;
(b) 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;
(c) income from seminars, lecturers, 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 center, or a research institute that is affiliated with an Institution of higher education;
(d) or income from service on advisory committee 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.

Please refer to the related Conflict of Interest Policy for Administrators and confer with the Director if you have questions about disclosure requirements of the College of the Holy Cross.

Institutional Responsibilities

1) Training – The Director shall:
(a) Inform each Investigator of the College’s policy on financial conflicts of interests.
(b) Inform each Investigator of the Investigator’s responsibilities regarding disclosure of significant financial interests and of these regulations.
(c) Require each Investigator to complete training regarding disclosure of significant financial interests and of these regulations prior to engaging in research related to any PHS or NSF-funded grant and at least every four years, and immediately when any of the following circumstances apply:

(i) The College revises its financial conflict of interest policies or procedures in any manner that affects the requirements of Investigators.
(ii) An Investigator is new to the College.
(iii) The College finds that an Investigator is not in compliance with the College’s financial conflict of interest policy or management plan.

2) Additional Responsibilities of the Director.
   (a) The Director 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 Director 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 PHS or NSF-funded research could be affected by the significant financial interest;
      (ii) Or 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 PHS or NSF-funded 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 Director 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.
      (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 College’s determination of a financial conflict of interest) and all actions under the College’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). 92.42 (b) and the NSF Grant Manual, §510g for different situations.
   (d) The Director 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 and including termination.
3) The Director shall provide initial and ongoing Financial Conflict of Interest reports to the PHS as required pursuant to 42 CFR § 50.605(b).

4) Use of Sub-recipients – If any part of the PHS-funded research is conducted through a subrecipient (e.g., subcontractors or consortium members), the Director 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 awarded 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 Financial Conflict of Interest reports to the PHS 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.

5) Whenever the College determines that it is unable to satisfactorily manage a conflict of interest, it will, as required by NSF, inform the NSF office of the General Counsel electronically via the NSF Fastlane system.
DEFINITIONS

“Entity” as used in the PHS 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 College, 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 NSF-funded research project.

“Institution”
For purposes of the Financial Conflict of Interest policy, “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 as an Investigator’s professional responsibilities on behalf of the College, and as defined by the College in this policy on Financial Conflict of Interest. It includes such activities as research, research consultation, teaching, professional practice, 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 at the College, who is responsible for the design, conduct, or reporting of research or proposed for such funding by certain Federal Agencies. Typically, this will include the Principal Investigator and co-Investigators, Sub-recipients and Collaborators. For the purposes of this disclosure requirement, the term “Investigator” includes the Investigator’s spouse and dependent children.

“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).

“National Science Foundation”
NSF means the National Science Foundation which is an independent federal agency created by Congress in 1950 to promote the progress of science, to advance the national health, prosperity and welfare (and) to secure the national defense.
“Research”

Research is any activity (described at 42 CFR 50.603) for which research funding is available from a PHS Awarding Component (e.g., NIH) or the National Science Foundation through a grant or cooperative agreement. It may include: a research grant, career development award, center grant, individual fellowship award, infrastructure award, Institutional training grant, program project, or research resources award.

“Senior/Key Personnel”

As referenced in the 2011 revised regulation, “Senior/Key Personnel” in PHS-funded research, Senior/Key Personnel means the Project Director/Principal Investigator (PD/DI) 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-funded agency by the Institution under the regulation.

“Sub-recipient”

A sub-recipient is an entity that receives a sub-award from the prime recipient under an award and is accountable to the prime recipient for the use of the Federal funds provided by the subaward.

Forms:

Title: Disclosure of Significant Financial Interest

Related Information:

Title: Responsibility of Applicants for Promoting Objectivity in Research
Title: Conflict of Interest Policy for Administrators
Title: PHS Granting Agencies
Title: NSF Proposal and Awards Policies and Procedures Guide

Policy # 100400-001
Date of Last Review Aug-01-2012