

Title: Financial Conflict of Interest Policy for PHS or NSF Grants; Reporting Harassment Issues

Policy Administrator: Director of Sponsored Research

Approved by: Provost and Dean of the College

Purpose:

The U.S. Department of Health and Human Services (HHS) regulation, [Responsibility of Applicants for Promoting Objectivity in Research for which Public Health Service Funding is Sought, 42 C.F.R. Part 50, Subpart F](#), promotes objectivity in research by establishing standards to provide a reasonable expectation that the design, conduct, or reporting of research and educational activities funded under grants or cooperative agreements of the Public Health Service (PHS) and related components (such as the National Institutes of Health (NIH) and Centers for Disease Control and Prevention (CDC)) will be free from bias resulting from any Investigator financial conflicts of interest. In addition, the National Science Foundation (NSF) establishes standards to ensure that research and educational activities funded by NSF grants and co-agreements are free from financial conflicts of interest.

This policy establishes requirements to ensure that the College of the Holy Cross (College) is in compliance with all requirements in applying for or receiving PHS (and related components such as NIH and CDC) or NSF funding and is applicable to any such proposals submitted and/or awards received. This policy applies to research and educational activities authorized under the Public Health Service Act, 42 U.S.C. 201 *et seq.*, or by the NSF, 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. Excluded from this policy is the PHS award program Small Business Innovative Research (SBIR).

Definitions:

Institution – Any domestic or foreign, public or private, entity or organization (excluding a Federal agency) that is applying for, or that receives, applicable funding from PHS or NSF as described above.

Investigator – The project director or principal investigator and any other person who is responsible for the design, conduct, or reporting of research or educational activities or proposed for such funding by PHS or NSF. Typically, this will include the principal investigator, and co-

principal investigators or co-project directors, subrecipients, consultants and collaborators.

Financial Conflict of Interest – A financial conflict of interest exists when the College, through the Director of Sponsored Research, reasonably determines that an Investigator’s significant financial interest related to a PHS or NSF-funded research project or educational activities and could directly and significantly affect the design, conduct or reporting of the PHS or NSF-funded research project or educational activities.

Institutional responsibilities – An Investigator's professional responsibilities on behalf of the Institution, including activities such 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.

Related to a PHS or NSF-funded research project or activity – A significant financial interest could be affected by the PHS or NSF-funded research or is in an entity whose financial interest could be affected by the research. A significant financial interest with an entity would be reasonably considered related to an Investigator's research project in circumstances such as the following: (a) the entity sponsors research at the College in which the Investigator is directly involved, (b) the entity has financial interests that could reasonably be considered to have a potential influence on the design, conduct or reporting of Investigator's research project, (c) the entity has a reasonable possibility of being financially affected by investigator's research project; (d) the entity makes gifts to the College that benefit Investigator's research project (which could include equipment gifts or loans), (e) the entity makes a product that is under study in research in which Investigator is involved, (f) the entity licenses intellectual property in which Investigator has a financial interest, and/or (g) the entity sponsors or makes a product that is under study in human subjects in which Investigator is directly or indirectly involved.

Subrecipient – An entity that receives a subaward from the College under a prime award and is accountable to the College for the use of the federal funds provided by the subaward.

Significant Financial Interest

1. A financial interest consisting of one or more of the following interests of the Investigator (when aggregated with 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/or the value of any equity interest in the entity as of the date of disclosure, when aggregated, exceeds \$5,000 or represents more than a 5% equity interest in the entity.
 - **remuneration** includes salary and any payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorship); and
 - **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.

- i. 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
 - ii. **Intellectual property rights and interests** (e.g., patents, copyrights), upon receipt of income related to such rights and interests.
2. The term "*significant financial interest*" **does not include** the following types of financial interests:
- o salary, royalties, or other remuneration paid by the Institution to the Investigator if the Investigator is currently employed or otherwise appointed by the Institution, including intellectual property rights assigned to the Institution and agreements to share in royalties related to such rights;
 - o any ownership interest in the Institution held by the Investigator, if the Institution is a commercial or for-profit organization;
 - o 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 center, or a research institute that is affiliated with an Institution of higher education;
 - o 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 center, or a research institute that is affiliated with an Institution of higher education; or
 - o with respect to PHS-funded research only, 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.

Procedures:

Investigator Responsibilities:

1. Required Disclosures.
 - a. Significant Financial Interests. Each Investigator:
 - i. who is planning to participate in the PHS or NSF-funded research or educational activities shall disclose 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 or educational activities by completing

and submitting a [Disclosure of Significant Financial Interests](#) to the Director of Sponsored Research.

- ii. who is participating in the PHS or NSF-funded research or educational activities shall complete and submit an updated [Disclosure of Significant Financial Interests](#):
 - A. 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 (i.e., 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).
 - B. within 30 days of discovering or acquiring (e.g., through purchase, marriage, or inheritance) a new significant financial interest.

Investigators must submit required significant financial interest disclosures to the Director of Sponsored Research. Upon review, if it is determined a potential conflict is present, the Director of Sponsored Research will devise a plan to manage or eliminate the conflict.

- a. Additional Disclosure. If the Investigator is the Primary Investigator, the Investigator shall advise the Director of Sponsored Research of any Financial Conflict of Interest with any sub-recipients or sub-awardees.
- b. Travel. Investigators who are planning to participate in PHS-funded research also must disclose the occurrence of any **reimbursed or sponsored travel** related to their institutional responsibilities; provided, however, that this 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. Disclosure includes, at a minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration. In accordance with this policy, the institutional official(s) 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-funded research. They must also submit an updated disclosure of reimbursed or sponsored travel within 30 days of each occurrence.

2. Training for Investigators Participating in PHS-Funded Research. Each Investigator participating in PHS-funded research shall attend College provided or other required training

on the regulations and their obligations under the regulations. This includes the requirement to complete the Financial Conflict of Interest training through the [CITI program](#). Training must be completed prior to engaging in the PHS-funded research, or for currently PHS-funded investigators completed prior to the award renewal or continuation funding. In addition, Investigator must attend updated training every four years. Training is required immediately when changes in this policy affect the requirements of Investigators, a researcher is new to the College or the College finds that an Investigator is not in compliance with this policy or a conflict management plan.

3. Management of Conflicts. Each Investigator shall participate in and comply with any College Financial Conflict of Interest Management Plan, as applicable, including any retrospective review and/or mitigation plan.

College Responsibilities:

1. Availability of Policy. The College shall maintain this policy as publicly available on its policy website.
2. Designated Official. The College has designated the Director of Sponsored Research to solicit and review disclosures of significant financial interests from each Investigator who is planning to participate in, or is participating in, PHS or NSF-funded research or educational activities.
3. Information for Investigators. The Director of Sponsored Research will inform each Investigator of this policy, the Investigator's disclosure responsibilities pertaining to significant financial interests, and of PHS regulations and NSF requirements, as applicable.
4. Solicitation of Disclosure; Review and Management of a Financial Conflict of Interests.
 - 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 or activities. The Director will determine if the significant financial interest is related to PHS or NSF-funded research or activities, and if so, whether a financial conflict of interest exists under the applicable requirements.
 - b. In the event that the Director determines that a financial conflict of interest is present, the Director will review the research or activity, the significant financial interest(s) and areas of conflict, and develop, implement, and monitor a management plan specifying the actions that have been, and shall be, taken to manage the conflict. The Director has the discretion to solicit the assistance of other administrators for the development of a management plan. The management plan will impose conditions or restrictions to

reduce, manage or eliminate the conflict through completion of the PHS or NSF-funded project. This can include, but is not limited to, monitoring by an independent third party capable of taking measures to protect the design, conduct, and reporting of the research or activity against bias resulting from the financial conflict of interest, modification of the research or activity plan, disqualification of personnel participation in the portion of PHS or NSF-funded research or activity that relates to the significant financial interest, reduction or elimination of the financial interest (e.g., sale of an equity interest), severance of the relationship that created the conflict, and /or public disclosure of the conflict of interest. The Investigator will be included in the development, negotiation and implementation of the management plan upon the understanding that the research or activity cannot begin or continue until all parties have agreed to the management plan.

- i. With respect to an NSF-funded project or activity, if the Director determines that imposing conditions or restrictions would either be ineffective or inequitable, and that the potential negative impacts that may arise from the significant financial interest are outweighed by interests of scientific progress, technology transfer, or public health and welfare, then the Director may allow the research or activity to go forward without imposing conditions after notifying the NSF general counsel's office.
- c. Whenever, in the course of an ongoing PHS or NSF-funded research project, an Investigator who is new to participating in the project discloses a significant financial interest or an existing Investigator discloses a new significant financial interest, the Director of Sponsored Research shall, within sixty (60) days, review the disclosure of the significant financial interest; determine whether it is related to PHS or NSF-funded research or activity; determine whether a financial conflict of interest exists; and, if so, implement, on at least an interim basis, a management plan that shall specify the actions that have been, and will be, taken to manage such financial conflict of interest. Depending on the nature of the significant financial interest, the Director of Sponsored Research may determine that additional interim measures are necessary with regard to the Investigator's participation in the PHS or NSF-funded research project between the date of disclosure and the completion of the review.
- d. Whenever the College identifies a significant financial interest that was not disclosed timely by an Investigator or, for whatever reason, was not previously reviewed by the Director of Sponsored Research during an ongoing PHS or NSF-funded research project (e.g., was not timely reviewed or reported by a subrecipient), the Director of Sponsored Research or other designated official(s) shall, within sixty (60) days review the significant financial interest, determine whether it is related to PHS or NSF-funded research or activity, determine whether a financial conflict of interest exist and, if so, implement, on at least an interim basis, a management plan that shall specify the actions that have been, and will be, taken to manage such financial conflict of interest going forward.

- e. Retrospective Review with respect to PHS Funded Research. In addition to the steps taken above, whenever a financial conflict of interest is not identified or managed in a timely manner with respect to a PHS-funded research project, the College shall, within 120 days of the determination of noncompliance, complete a retrospective review of the Investigator's activities and the PHS-funded research project in accordance with 42 C.F.R. §50.605(a)(3)(ii) to determine whether any PHS-funded research or portion thereof, conducted during the time period of the noncompliance, was biased in the design, conduct, or reporting of such research or activity. Additional interim measures may be imposed pending completion of the retrospective review. The College shall update previously submitted financial conflict of interest reports, specifying actions that will be taken to manage the conflict going forward. If bias is found, the College shall notify and submit a mitigation report to the PHS awarding component in accordance with 42 C.F.R. §50.605(a)(3)(iii).
5. Subrecipients. The College shall take reasonable steps to ensure the compliance of all subrecipients (e.g., subcontractors or consortium members) with applicable federal guidelines pertaining to financial conflict of interests.
- a. The Director of Sponsored Research will ensure that a written agreement is executed to designate whether the subrecipient will follow this policy or the policy of their home institution and, if the subrecipient will follow its policy, for the subrecipient to certify that its policy complies with 42 CFR Part 50, Subpart F or the NSF requirements, as applicable.
 - i. If the subrecipient's Investigators must comply with subrecipient's financial conflict of interest policy, the agreement shall specify time period(s) for the subrecipient to report all identified financial conflicts of interest to the College. Such time period(s) shall be sufficient to enable the College to provide timely financial conflict of interest reports, as necessary, to the PHS/NSF as required by law.
 - ii. If the subrecipient must comply with this policy, the agreement shall specify time period(s) for the subrecipient to submit all Investigator disclosures of significant financial interests to the College. Such time period(s) shall be sufficient to provide the College ample review time to comply with its review, management and reporting obligations. The agreement will state that the subrecipient will comply with the conflict management plan designated by the College.
6. Reporting of Financial Conflicts of Interest. The Director of Sponsored Research shall report financial conflicts of interest to (a) the PHS awarding component in accordance with 42 C.F.R. Part 50, Subpart F, including, but not limited to, those relating to subrecipient Investigators and (b) the NSF general counsel's office if the Director determines that imposing

conditions or restrictions would either be ineffective or inequitable, and that the potential negative impacts that may arise from the significant financial interest are outweighed by interests of scientific progress, technology transfer, or public health and welfare and the Director will allow the research or activity to go forward without imposing conditions.

7. Public Accessibility regarding PHS-Funded Research Projects. Prior to the College's expenditure of any funds under a PHS-funded research project or activity, the Director of Sponsored Research shall ensure public accessibility, via a publicly accessible website or written response to any requestor within five business days of a request or as required by law. This information will include: the Investigator's name; the Investigator's title and role with respect to the research project; the name of the entity in which the significant financial interest is held; the nature of the significant financial interest; and the approximate dollar value of the significant financial interest (in pre-specified dollar ranges), or a statement that a value cannot be readily determined. This information will remain publicly accessible for at least three years from the date that it was most recently updated.
8. Record Retention. The Director of Sponsored Research shall maintain records of all financial disclosures hereunder and the actions taken to review, respond, resolve or manage such disclosure (whether or not a disclosure resulted in the Institution's determination of a financial conflict of interest) and/or conflict for three (3) years from the date of termination or completion of the grant to which they are relevant or until any federal action involving the records is resolved where longer. CITI completion reports shall be maintained in the Office of Sponsored Research. The Director of Sponsored Research will make information available, promptly upon request, to the U.S. Department of Health and Human Services relating to any Investigator disclosure of financial interests and the College's review of, and response to, such disclosure, whether or not the disclosure resulted in the College's determination of a financial conflict of interest.
9. Disciplinary Sanctions and Administrative Actions. PHS and NSF require the College to have adequate enforcement mechanisms and provide sanctions where appropriate. The College, as determined by the Provost or designee, may take disciplinary action and/or other administrative action upon the College's determination of an Investigator's violation of this policy.
10. Reporting of Harassment Issues. NSF requires the College to notify NSF in the event that a principal investigator or co principal investigator identified on an NSF award is found to have violated any College policy or applicable law, regulation or executive order regarding sexual assault, sexual harassment or other form of harassment, including, but not limited to, any temporary/interim suspension or permanent removal of such individual relating to teaching, advising, mentoring, research, management, administrative duties or presence on campus. The Provost or designee shall be responsible for reporting to such issues to NSF in accordance with NSF Article X.

Applicable Federal Regulations and Policies

NIH Financial Conflict of Interest Policy –

<http://grants.nih.gov/grants/policy/coi/index.htm>

NSF Financial Conflict of Interest Policy –

http://www.nsf.gov/pubs/policydocs/pappguide/nsf16001/aag_4.jsp#IVA

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