



HOBART AND WILLIAM SMITH
COLLEGES

**Financial Conflict of Interest Policy
for Investigators Conducting Research Supported by Public Health Service Funding**

Background

In 1995, the Public Health Service (PHS) and the Office of the Secretary of the U.S. Department of Health and Human Services (HHS) published regulations in 42 CFR part 50, subpart F and 45 CFR part 94, that are designed to promote objectivity in PHS-funded research. To address the growing complexity of biomedical and behavioral research, the increased interaction among Government, research institutions, and the private sector in attaining common public health goals while meeting public expectations for research integrity, as well as increased public scrutiny and a need to strengthen accountability, the HHS published revised regulations on the *Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is Sought and Responsible Prospective Contractors*. This final rule was effective as of September 26, 2011 and is commonly known as the Financial Conflict of Interest (FCOI) regulation. The final rule expands and adds transparency to Investigators' disclosure of Significant Financial Interests (SFIs), enhances regulatory compliance and effective institutional oversight and management of Investigators' FCOIs, and increases the HHS compliance oversight. These regulations establish new standards and clarify previously established standards to be followed by Institutions that apply for or receive funding from PHS Awarding Components, including the National Institutes of Health (NIH), for grants, cooperative agreements, and contracts.

An Institution applying for or receiving NIH funding must be in compliance with the revised regulatory requirements no later than 365 days after publication of the regulation in the Federal Register, i.e., August 24, 2012, and immediately upon making the Institution's FCOI Policy publicly accessible as described in 42 CFR part 50.604(a).

Hobart and William Smith Colleges FCOI Policy Statement for PHS/NIH-Funded Activities

This policy is intended to signify that HWS, in applying for or receiving PHS funding from a grant or cooperative agreement that is covered by the 2011 revised regulation, has documented procedures in place and made available on a publicly accessible website to ensure full compliance with all regulatory requirements. As documented in the NIH Guide Notice NOT-OD- 18-160, the FCOI regulations apply to each institution, domestic and foreign, that applies for or receives NIH research funding in the form of grants or cooperative agreements, and applies to both prime and subrecipient institutions, domestic or foreign, and through implementation, to each Investigator who is planning to participate in, or is participating in, such research (excluding Phase I Small Business Innovative Research and Small Business Technology Transfer applications or awards).

Investigator (as defined below) activities shall be conducted in a manner that avoids any inappropriate FCOI. FCOIs may occur when there is a divergence between a faculty member's private interests and professional services to the Colleges. An FCOI exists when the recipient's designated official(s) reasonably determines that an Investigator's significant financial interest (as defined below) could directly and significantly affect the design, conduct, or reporting of the PHS-funded research. The NIH requires recipient institutions and Investigators (except Phase I SBIR/STTR applicants and recipients) to comply with the requirements of 42 CFR 50, Subpart F, Promoting Objectivity in Research (FCOI regulation), as implemented in the 2011 Final Rule for grants and cooperative agreements.

This policy is designed to assist the Colleges and Investigators in identifying potential and actual FCOIs and to ensuring compliance with government regulations by establishing standards that provide a reasonable expectation that the design, conduct, or reporting of research funded under PHS grants or cooperative agreements will be free from bias resulting from any conflicting financial interest of an Investigator. The Colleges are required to maintain an up-to-date, written, enforced policy on FCOIs that complies with the FCOI regulation, and make the policy available via a publicly accessible website.

Procedures

1) Scope

This policy is applicable to all Investigators applying for or receiving PHS funding from a grant or cooperative agreement that is covered by the 2011 revised regulation.

An **Investigator** is someone defined as the Project Director or Principal Investigator (PD/PI) and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research funded by the PHS (e.g., NIH), or proposed for such funding, which may include, for example, other key personnel, collaborators, or consultants. All Investigators are required to disclose to the Colleges' Research Integrity Officer¹ (RIO) all Significant Financial Interests (SFIs) of the Investigator and/or the Investigator's spouse, domestic partner, and/or dependent children. See paragraph 3 "Timing of Disclosures."

A **subrecipient** relationship is established when federal funds flow down from an awardee institution to another individual or entity, and the subrecipient will be conducting a substantive portion of the PHS-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 FCOI regulation applies to subrecipients (e.g., subcontractors or consortium members) per 42 CFR 50.604 (c). The awardee Institution is responsible for

¹ For more information and the definition of RIO, see the HWS Scientific Misconduct Policy at https://www.hws.edu/offices/pdf/ri_policy.pdf

ensuring subrecipient's compliance with the regulation and reporting identified FCOIs for subrecipient Investigators to the NIH. Terms shall be written into all contractual agreements between HWS and the subrecipient establishing whether the FCOI Policy of the awardee Institution or of the subrecipient will apply to subrecipient investigators. Furthermore, the terms of the agreement shall state the time periods to meet disclosure and/or FCOI reporting requirements.

The Institution (HWS) is responsible for monitoring subrecipient's compliance with the FCOI regulation, management plans, and for reporting all identified FCOIs to the NIH.

2) Institutional Responsibilities

“Institutional responsibilities” means an Investigator's professional responsibilities on behalf of HWS, and as defined by HWS in its policy on FCOI, which includes activities such as research, research consultation, teaching, professional practice, institutional committee memberships, and service on panels such as the Human Subjects Research Committee at HWS (also known as the Institutional Review Board, or IRB).

3) Disclosure of Significant Financial Interests

- a) Definition:** FCOI means a significant financial interest (SFI) that could directly and significantly affect the design, conduct, or reporting of PHS-funded research. An SFI is 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, an SFI exists if the value of any remuneration received from the entity in the 12 months preceding the disclosure *and* the value of any equity interest in the entity as of the date of the disclosure, when aggregated, exceeds \$5,000. Remuneration includes any 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, an SFI exists if the value of any remuneration received from the entity in the 12 months preceding the disclosure, when aggregated, exceeds \$5,000, *or* when the Investigator (or the Investigator's spouse, domestic partner, and/or dependent children) holds *any* equity interest, regardless of dollar value.
 - iii)** Intellectual property rights and interests (e.g., patents and copyrights) upon receipt of income related to such rights and interests.
 - iv)** All occurrences 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 the Investigator's institutional

responsibilities must also be disclosed, with the *exception* of any travel 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 center/institute affiliated with an institution of higher education. Travel that is reimbursed by HWS from a sponsored fund account whose sponsor is an entity that is not one of those exempt entities shall be treated as an SFI. HWS's FCOI policy requires that the Investigator must disclose the purpose of the trip, the identity of the sponsor and/or organizer, the destination and its duration. The RIO will determine if further information is needed and may request additional information, including a determination or disclosure of the estimated cost or monetary value of the travel in order to determine whether travel constitutes an FCOI with the PHS-funded research. Investigators must furnish any additional information upon request.

- v) All foreign financial interests (which includes income from seminars, lectures, or teaching engagements, income from service on advisory committees or review panels, and reimbursed or sponsored travel) received from any foreign entity, including foreign institutions of higher education or foreign government (which includes local, provincial, or equivalent governments of another country) when such income meets the threshold for disclosure (i.e., income exceeds \$5,000).
- b) Exclusions: The term “Significant Financial Interest” does not include the following types of financial interests:
- i) Salary, royalties, or other remuneration paid by HWS to the Investigator if the Investigator is currently employed or otherwise appointed by the Colleges, including intellectual property rights assigned to the Colleges and agreements to share in royalties related to such rights in conformity with the Colleges’ Intellectual Property policy (see https://www.hws.edu/offices/pdf/IP_Policy.pdf).
 - ii) Income from investment vehicles, such as mutual funds or 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 federal, state, or local government agencies, institutions of higher education as defined at 20 U.S.C. 1001(a), academic teaching hospitals, medical centers, or research institutes affiliated with institutions of higher education.
- (1) As clarified in NIH Guide Notice NOT-OD-18-160, the FCOI regulation refers to exclusions of institutions of higher education as defined in 20 U.S.C. 1001(a) or a federal, state or local government agency when disclosing financial interests. However, these references refer to a U.S. Institution of higher education or a federal, state, or local government agency within the U.S. Therefore, Investigators, including subrecipient Investigators, **must disclose** all financial interests received from a foreign institution of higher education or the government of another country (which includes local, provincial, or equivalent governments of another country).

iv) Income from service on advisory committees or review panels for federal, state, or local government agencies, institutions of higher education as defined at 20 U.S.C. 1001(a), academic teaching hospitals, medical centers, or research institutes affiliated with institutions of higher education.

(1) As clarified in NIH Guide Notice NOT-OD-18-160, the FCOI regulation refers to exclusions of institutions of higher education as defined in 20 U.S.C. 1001(a) or a federal, state or local government agency when disclosing financial interests. However, these references refer to a U.S. Institution of higher education or a federal, state, or local government agency within the U.S. Therefore, Investigators, including subrecipient Investigators, must disclose all financial interests received from a foreign institution of higher education or the government of another country (which includes local, provincial, or equivalent governments of another country).

4) Method and Timing of Disclosures and Maintenance of Records

- a) Prior to the submission of a proposal for an NIH grant or cooperative agreement, Investigators must complete the Disclosure Statement for HWS PHS Researchers located here: <https://campus.hws.edu/GrantCompliance/Account/Login?ReturnUrl=%2fGrantCompliance>. The Disclosure will be reviewed by the Director of Sponsored Programs as part of the institutional proposal approval process.²
- b) Investigators must provide all required financial disclosures *no later than* at the time of application for PHS-funded research.
- c) Investigators must update and resubmit financial disclosures:
- i) Within 30 days of their discovering or acquiring (e.g., through purchase, marriage, or inheritance) a new SFI; and
 - ii) Annually during the period of the award, beginning upon notification of a new award and annually on the award date thereafter.

² For more information about the HWS internal proposal approval process, see the Sponsored Programs website at <https://www.hws.edu/offices/sponsored-programs/>

- d) HWS will maintain all FCOI-related records for at least three years from the date of that the final expenditures report is submitted to the NIH, and from other dates as specified throughout this policy and as specified in 45 CFR 75.361, where applicable.

5) Process for the Review and Management of Financial Disclosures

- a) Determination: The RIO shall solicit and review each disclosed SFI (including those of the Investigator's spouse and dependent children) related to an Investigator's institutional responsibilities, determine whether an Investigator's SFI is related to PHS-funded research, and, if so, determine whether the SFI is an FCOI (as defined below). The RIO will determine what conditions or restrictions, if any, should be imposed by HWS to manage, reduce, or eliminate the FCOI.
- b) Definition: An FCOI exists when the Institution, through its RIO, reasonably determines that an Investigator's SFI is related to an NIH-funded research project and could directly and significantly affect or bias the design, conduct, or reporting of the NIH-funded research activities.
- c) Management of Financial Conflicts of Interest: If the RIO determines that an SFI is an FCOI, the RIO will consult with the HWS Deciding Official (DO)³ to review the PHS-funded research activities, the disclosed SFIs, and the areas of identified conflict, in order to develop an informed plan for the management of the FCOI (the "Management Plan") to support the goals of the Colleges as a recipient of PHS funds and the continued objective pursuit of research. A Management Plan may be required for an Investigator who is new to participating in the PHS-funded research project or for an existing Investigator who discloses a new SFI.
 - i) When required, a Management Plan will be implemented within sixty days whenever HWS identifies an SFI that was not disclosed timely by an Investigator or not previously reviewed by the Institution (see Retrospective Review, below). In accordance with the Colleges' responsibility for subrecipient financial disclosures (see Scope, above), the agreement between HWS and the subrecipient will be amended to include requirements to comply with any applicable Management Plan and continued annual financial disclosures until completion of the project.
 - ii) The Investigator will be consulted as to the design and implementation of the Management Plan, and the Investigator must agree in writing to the plan before PHS-funded research can proceed; if the RIO, DO, and Investigator cannot agree to the terms of a Management Plan, the PHS-funded research activities will be paused, and the relevant regulatory body and funding agency will be notified.

³ For more information and the definition of Deciding Official, see the HWS Scientific Misconduct Policy at https://www.hws.edu/offices/pdf/ri_policy.pdf

iii) Conditions or restrictions that might be imposed to manage an Investigator's FCOI include, but are not limited to:

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

d) Retrospective Reviews:

- i) Determination:** Whenever an FCOI is not identified or managed in a timely manner, including failure by the Investigator to disclose an SFI that is determined by HWS to constitute an FCOI, failure by HWS to review or manage such an FCOI, and/or failure by the Investigator to comply with an FCOI management plan, HWS shall, within 120 days of the Colleges' determination of noncompliance, complete a Retrospective Review of the Investigator's activities and the PHS-funded research project 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.
- ii) Documentation:** HWS shall document the Retrospective Review which will include at least the following elements: Project Number, Project Title, PD/PI or contact PD/PI if a multiple PD/PI model is used; name of the Investigator with the FCOI; name of the entity with which the Investigator has an FCOI; reason(s) for the retrospective review; detailed methodology used for the retrospective review (e.g., methodology of the review process, composition of the review panel, documents reviewed, etc.); findings of the review; and conclusions of the review.
- iii) Procedures:** The RIO will notify the Investigator in writing of the intent to conduct a retrospective review within 30 days of the Colleges' determination of noncompliance. At the time of notification, the Investigator will be informed of the composition of the review panel and the methodology to be used for the retrospective review. The Investigator shall have 15 days following receipt of notification to respond with any requests to modify the composition of the review panel or request additional information concerning the determination of noncompliance and methodology to be used during the retrospective review. The RIO will have 15 days to respond to the

Investigator's inquiries and the RIO will make the final determination of the composition of the review panel and methodology to be used for the retrospective review. The retrospective review will commence no later than 61 days after the Colleges' determination of noncompliance.

- iv) Findings and Reporting: If bias is found, the Institution must notify the PHS awarding component promptly and submit a mitigation report. For FCOIs previously reported to the NIH, the mitigation report is submitted as a "Revised FCOI Report." The mitigation report must include, at a minimum, the key elements documented in the retrospective review above and a description of the impact of the bias on the research project and the Institution's plan of action or actions taken to eliminate or mitigate the effect of the bias (i.e., impact on the research project; extent of harm, including any qualitative and quantitative data to support any actual or possible future harm; analysis of whether the research project is salvageable). Thereafter, the Institution will submit FCOI reports annually as prescribed by the regulation. When bias is not found following the completion of a Retrospective Review, the recipient should not submit a "Revised FCOI Report" to notify NIH that either the Retrospective Review has been completed or that bias is not found.
- e) Enforcement Mechanisms and Remedies, and Noncompliance: In the event an Investigator fails to comply with HWS's FCOI Policy, including any applicable Management Plan, the DO will determine appropriate sanctions or other administrative actions to ensure Investigator compliance.

6) Reporting Financial Conflicts of Interest

- a) Sponsoring Agency: SFIs that are determined by the RIO to be Financial Conflicts of Interest will be reported to the sponsoring agency within 60 days of the original disclosure.
 - i) Annual Financial Conflict of Interest reports shall be submitted through the NIH eRA Commons system in accordance with agency requirements.
- b) Public Request: Prior to the Institution's expenditure of any funds under a PHS-funded research project, the Institution shall ensure public accessibility or written response within five business days of a request for information concerning any SFI disclosed to the Institution that meets the following three criteria:
 - i) The SFI was disclosed and is still held by the senior/key personnel for the PHS-funded research project identified by the Institution in the grant application, progress report, or any other required report submitted to the relevant PHS agency
 - ii) The Institution determines that the SFI is related to the PHS-funded research
 - iii) The Institution determines that the SFI is a Financial Conflict of Interest

- c) In any case in which the HHS determines that a PHS-funded research project of clinical research whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment has been designed, conducted, or reported by an Investigator with an FCOI that was not managed or reported by HWS as required by the regulation, the Colleges shall require the Investigator involve to:
 - i) Disclose the FCOI in each public presentation of the results of the research, and
 - ii) Request an addendum to previously published presentations

7) Investigator Training

The FCOI regulations require that all Investigators complete training on the *Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is Sought* guidelines and the Institutional policy implemented as a response to this regulation. The Office of Sponsored Programs will notify Investigators in advance of when they are due to complete the training requirement. HWS requires Investigators to complete the NIH Office on Extramural Research FCOI Training Tutorial. Each Investigator must complete training prior to engaging in PHS-funded research and at least every four years, and immediately under any of the circumstances designated below:

- i) HWS's FCOI Policy changes in a manner that affects Investigator requirements
- ii) An Investigator is new to HWS or the PHS-funded research project
- iii) HWS finds that an Investigator is not in compliance with the Colleges' FCOI policy or management plan

8) Additional Resources

- a) To learn more about the FCOI regulations, Investigators are encouraged to review these resources:
 - i) NIH Financial Conflict of Interest Website:
<http://grants.nih.gov/grants/policy/coi/index.htm>
 - ii) NIH Financial Conflict of Interest Tutorial:
https://grants.nih.gov/grants/policy/coi/tutorial2018/story_html5.html

- iii) NIH Grants Policy Statement: 4.1.10 Financial Conflict of Interest
https://grants.nih.gov/grants/policy/nihgps/HTML5/section_4/4.1.10_financial_conflict_of_interest.htm?Highlight=fcoi
- iv) Final Rule: Federal Register: Responsibility of Applicants for Promoting Objectivity in Research for which Public Health Service Funding is Sought and Responsible Prospective Contractors
<http://www.gpo.gov/fdsys/pkg/FR-2011-08-25/pdf/2011-21633.pdf>
- v) Financial Conflict of Interest: Investigator Disclosures of Foreign Financial Interests (NOT-OD-18-160)
<https://grants.nih.gov/grants/guide/notice-files/NOT-OD-18-160.html>