

Woods Hole Oceanographic Institution
Addendum to WHOI Conflict of Interest and Outside Professional Activities Policy
Applicable to Public Health Services Funded Investigators

PURPOSE

This Addendum describes the Conflict of Interest (COI) policies and procedures for reporting and managing COI of Investigators, who under the auspices of Woods Hole Oceanographic Institution (WHOI), apply for a grant or cooperative agreement from the Public Health Service of the U.S. Department of Health and Human Services (PHS), including the National Institutes of Health (NIH). The objective is to promote research that is free from bias resulting from financial conflict of interest of an individual and to describe the implementation of the federal regulations in 42 CFR Part 50 and 45 CFR Part 94.

This Addendum applies to all persons responsible for designing, conducting or reporting PHS-funded research under the auspices of Woods Hole Oceanographic Institution.

DEFINITIONS

Financial Interest (FI) Anything of monetary value whether or not the value is readily ascertainable. These include:

- remuneration (e.g., salary, consulting fees, honoraria, paid authorship fees) from a publicly traded or a non-publicly traded entity,
- equity interests (e.g., stocks, stock options or other ownership interest),
- Intellectual property rights (e.g., salaries, royalties),
- reimbursed or sponsored travel.

See definition of Significant Financial Interest (below) for limits and exclusions.

Financial Conflict of Interest (FCOI) A Significant Financial Interest (see definition page 2) that could directly and significantly affect the design, conduct or reporting of PHS-funded Research.

Institutional Official Individual within WHOI who is responsible for the solicitation and review of disclosures of significant financial interests that are related to the Investigator's institutional responsibilities. These financial interests include those of the Investigator's spouse and dependents. For the purposes of this policy, the Institutional Official is designated as the Director of Research (DoR) or other such individual(s) as WHOI may designate in writing.

Institutional Responsibilities Investigator's professional responsibilities associated with his or her WHOI appointment or position, such as research, teaching, administration, and service on WHOI committees or external committees or panels.

Investigator Project director or Principal Investigator and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of PHS-funded Research, or proposals for such funding. This may include post-doctoral fellows, graduate students, technicians, collaborators or consultants if they have such responsibilities.

Manage Action taken to address a financial conflict of interest, which can include reducing or eliminating the financial conflict of interest to ensure, to the extent possible, that the design, conduct, and reporting of research will be free from bias.

PHS 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, including the National Institutes of Health (NIH), and Center for Disease Control (CDC), and Food and Drug Administration (FDA). List of agencies can be found on http://nrc59.nas.edu/pub/fcoi_agencies_phs_regs.html

PHS-Funded Research Any research funded by or proposed to be funded by the PHS, including without limitation NIH awards. The term includes any Research for which funding is available from a PHS awarding component through a grant or cooperative agreement, whether authorized under the PHS Act or other statutory authority, such as a research grant, career development award, center grant, individual fellowship award, infrastructure award, institutional training grant, program project, or research resources award. For purposes of this Addendum, the term shall not include Phase 1 Small Business Innovative Research (SBIR) or Small Business Technology Transfer (STTR) applications or awards. (<http://grants.nih.gov/grants/funding/sbir.htm>)

Research A systematic investigation, study or experiment designed to develop or contribute to generalizable knowledge relating broadly to public health, including behavioral and social-sciences 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). Research includes any activity for which funding is available from a PHS Organization funding unit either through a grant or cooperative agreement (e.g., 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 Project director (PD) or Principal Investigator (PI) and any other person identified as senior/key personnel by WHOI in the grant application, contract proposal, contract, progress report, or any other reports submitted to the PHS by WHOI for PHS research.

Significant Financial Interest (SFI) Any financial interest (see above) that reasonably appears to be related to the Investigator's responsibilities at WHOI and consists of one or more of the following interests of an Investigator, or the Investigator's spouse or dependent children.

Types of significant financial interests are:

i. Remuneration and equities of a publicly traded entity that exceed \$5,000 when aggregated in the 12 months preceding the disclosure of the SFI.

- a. Remuneration is salary and any payment for services not identified as salary (e.g., consulting fees, honoraria, paid authorship)
- b. Equities are stocks, stock options, or other ownership interests as determined through reference to public prices or other reason measures of fair market value.

Exempted is income from seminars, lectures, teaching engagements, service on advisory committees or review panels that are 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.

Exempted is income from investment vehicles, such as mutual funds and retirement accounts, as long as the Investigator (or Investigator's spouse or dependent children) does not directly control the investment decisions made in these vehicles.

- ii. Remuneration, as described above, from a *non-publicly* traded entity that exceeds \$5,000 in the 12 months preceding the disclosure of the SFI, or when the Investigator (or the Investigator's spouse or dependent children) holds **any equity** interest (e.g., stock, stock options, or other ownership interests) in the entity.

Exempted is income from seminars, lectures, teaching engagements, service on advisory committees or review panels that are 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.

Exempted is income from investment vehicles, such as mutual funds and retirement accounts, as long as the Investigator (or Investigator's spouse or dependent children) does not directly control the investment decisions made in these vehicles.

- iii. Intellectual property rights and interests (e.g., patents, copyrights, royalties) upon receipt of income related to such rights and interests that exceed \$5,000.

Exempted are salaries, royalties, or other income paid by WHOI to the Investigator if the Investigator is currently employed or appointed by WHOI. This includes intellectual property rights assigned to WHOI and agreements to share in royalties related to such rights.

- iv. Reimbursed or sponsored travel related to an Investigator's responsibilities at WHOI and exceeds \$5,000 when aggregated per entity. Included is sponsored travel that is paid on behalf of the Investigator and not reimbursed to the Investigator so that the exact monetary value may not be readily available.

Exempted is travel that is reimbursed or sponsored by a U.S. Federal, state or local government agency, U.S. institutions or research institutes affiliated with institutions of higher education.

CONFLICT OF INTEREST

This Addendum to WHOI's COI Policy provides specific requirements for Investigators conducting PHS research and mechanisms for Investigators and WHOI to manage any FCOI. All PHS Investigators are expected to be familiar with, and abide by, the provisions of this policy. An Investigator should discuss questions about conflicts of interest with their Department Administrator or the Director of Research, if necessary.

This policy is predicated on the expectation that Investigators should conduct their affairs so as to avoid or minimize conflicts of interest, and must respond appropriately when conflicts of interest arise. To that end, this policy informs Investigators about situations that generate conflicts of interest related to

research, provides mechanisms for Investigators and the Institution to manage those conflicts of interest that arise, and describes situations that are prohibited.

INVESTIGATOR RESPONSIBILITIES

A. Reporting

Before applying for a PHS sponsored project or before starting a PHS-sponsored projects or applications for PHS-sponsored projects, the key Investigators must disclose significant financial interests (SFI) (including financial interests of Investigator's spouse and dependent children) that are reasonably related to the Investigator's responsibilities at WHOI on an Addendum PHS Financial Interest Report (PHS-AFIR) [Addendum Financial Interest Report \(pdf\)](#). The Director of Research (and COI Research Committee) will determine whether a significant financial interest is a financial conflict of interest (FCOI) or could affect the design, conduct or reporting of the PHS-Funded Research (see below). WHOI will not submit a research proposal unless the Investigator(s) have submitted a disclosure form and taken the training described below.

Investigators are required to submit a newly completed PHS Addendum Financial Interest Report (PHS-AFIR) online and notify their Department Administrator of its completion

- *annually* by the required deadline (minimum requirement).
- if there is a *change in existing financial interests* (through purchase, marriage, inheritance). The form must be submitted to the DoR within 30 days of the change.
- if *submitting a PHS proposal* and an up-to-date Financial Interest (PHS) form is not on file. A completed form must be submitted at or before the time of submission of the proposal or contract to a PHS agency.
- if *newly appointed* WHOI staff or newly assigned as an Investigator on a PHS project. The PHS-AFIR must be submitted within 30 days of the start date.
- to report *nonexempt travel* (see page 1) within 30 days of completing the travel. The disclosure should include the purpose of the trip, the identity of the sponsor/organizer, the destination and the duration.

B. Training

Training includes reading this document and taking the NIH [FCOI tutorial](http://grants.nih.gov/grants/policy/coi/tutorial2011/fcoi.htm) (<http://grants.nih.gov/grants/policy/coi/tutorial2011/fcoi.htm>). Upon completion of the tutorial, the Investigator **prints a certificate for his/her records and sends a copy of the certificate** to the Department Administrator. Training and reading this policy and the Investigator's PHS-FIR must be completed

- prior to engaging in research funded by PHS, and at least every four (4) years thereafter,

- within a reasonable period (60 days), if this policy is substantively amended in a manner that affects the requirements of Investigators,
- if the Investigator is newly appointed to WHOI,
- if it is determined that the Investigator has not complied with this policy or with a management plan related to their activities.

C. Comply with or appeal a management plan

Upon receiving a decision from the COI Review Committee of a FCOI, the Investigator must comply with the proposed management plan, or submit a written appeal within 10 days of the receipt of the management plan. Funding will not be dispersed until the Investigator agrees to comply with the management plan.

The appeal should contain the reason for the appeal, the specifics that are being appealed, suggestions for changes to the management plan, or additional information that is relevant to the decision by the COI Review Committee. The decision by the DoR is final and no further appeal can be made.

INSTITUTION RESPONSIBILITIES

A. Review FCOI

COI Review Committee – The COI Review Committee will have representatives from the Science Departments, Grant and Contract Services, the Controller’s Office and the Director of Research Office. The DoR will appoint members to the Review committee for four (4) year renewable terms. The Committee will have at least five (5) voting members with relevant research experience or administrative responsibility. The COI Review Committee may use guidance from other sources (e.g., Technology Transfer Office, CFO, legal counsel) as needed, and the Committee will act on a majority vote by written or electronic consent of its members.

Before WHOI disperses any funds for a PHS-funded research project, the DoR or an individual acting through the DoR or the COI Review Committee, will review the Investigator’s PHS-AFIR and any other information relevant to the review (e.g., research proposal).

- If no SFI exists, the report does not require further consideration.
- If there is a SFI that has no real or apparent COI, or can be easily addressed by standard management plans (e.g., disclosure interest to journal publishers), the Committee will send notification of the management plan.
- If an Investigator’s disclosure is a FCOI (i.e., a SFI that could significantly affect the design, conduct or reporting of the PHS-Funded Research), the COI Review Committee will recommend a management plan to the DoR through a written report. The DoR may request clarification or supplementation and will accept, reject or modify the COI Review Committee’s determination and recommendation. The DoR will make a final determination in writing and specify the conditions or restrictions necessary to manage the FCOI.

The Committee will provide copies of the report to the Investigator, Chair of the Investigator's department, DoR and the WHOI Office of Grant & Contract Services (GCS).

B. Management of Financial Conflict of Interests

Based on the decision of the COI Review Committee, management measures may include

- Disclosure of external commitment to fellow researchers, students involved in the research activity, journal publishers and when presenting or publishing the results
- Modification of the research plan
- Change in personnel or personnel responsibilities; or require the Investigator to abstain from certain decisions regarding the project design, execution or reporting
- Reduction or elimination of the financial interest (e.g., sale of an equity interest)
- Severance of commitments or relationships that create financial conflicts
- Assignment of an independent monitor(s) to protect the design, conduct and reporting of the research against bias results from the FCOI.

The management plan will name the person responsible (e.g., Department Chair) for overseeing the plan implementation, and who will report to the DoR and COI Review Committee at specified intervals on the compliance of the management plan. Any monitoring activity will state

- a. the person or persons who will monitor the plan,
- b. how the monitoring will be done,
- c. the records to be kept on file,
- d. the reports to be submitted to the COI Committee.

Investigator compliance with the management plan will be monitored on an ongoing basis until the completion of the PHS-funded research.

C. New SFIs during ongoing PHS-Funded Research

Whenever, in the course of ongoing PHS-funded Research, an Investigator who is new to participating in the PHS-funded research *discloses an SFI* or an existing Investigator discloses *a new SFI*, the Department Chair with the assistance of the Department Administrator will do the following, acting directly or in conjunction with the COI Review Committee, within sixty (60) days:

- review the SFI;
- determine whether it is related to PHS-Funded Research;
- determine whether a FCOI exists; and,
- if so, implement a management plan that shall specify the actions that have been, and will be, taken to manage the FCOI.

D. Investigator Non-Compliance

In the event of an Investigator's failure to comply with this Policy, the DoR may suspend all relevant activities or take other disciplinary action until the matter is resolved or other action deemed appropriate by the DoR or COI Review Committee is implemented.

The DoR or COI Review Committee decision to impose sanctions on an Investigator because of failure to comply with this Policy, or failure to comply with the decision, will be described in a written explanation of the decision to the Investigator, COI Review Committee and, where applicable, the DoR will notify the individual of the right to appeal the decision. The DoR will promptly notify the PHS Awarding agency (e.g., NIH) of the action taken or to be taken. If the funding for the research is from a prime PHS awardee, such notification shall be made promptly to the prime awardee prior to the expenditure of any funds and within sixty (60) days of any subsequently identified FCOI such that the prime awardee may fulfill their reporting obligations to the PHS.

E. Retrospective Review

If the DoR determines that a FCOI was not identified or managed in a timely manner, including but not limited to an Investigator's failure to disclose a SFI that is determined to be a FCOI, or failure by an Investigator to materially comply with a management plan for a FCOI, the COI Review Committee will complete a retrospective review of the Investigator's activities and the PHS-funded research project to determine whether the research conducted during the period of non-compliance was biased in the design, conduct or reporting of the research.

Documentation of the retrospective review shall include:

- the project number,
- project title,
- PI,
- name of Investigator with the FCOI,
- name of the entity with which the Investigator has the Financial Conflict of Interest,
- reason(s) for the retrospective review,
- detailed methodology used for the retrospective review,
- findings and conclusions of the review.

The DoR will update any previously submitted report to the PHS or the prime PHS-awardee relating to the research, specifying the actions that will be taken to manage the FCOI going forward. This retrospective review will be completed in the manner and within sixty (60) days. If bias is found, WHOI will promptly notify the PHS Awarding Component and submit a mitigation report in accordance with the PHS regulations. The mitigation report will identify:

- elements documented in the retrospective review,
- a description of the impact of the bias on the research project,
- the plan of action to eliminate or mitigate the effect of the bias.

F. Subrecipients

If WHOI is the awardee and conducts PHS-Funded Research through a subrecipient (e.g. subcontractors or consortium members), WHOI Office of Grants and Contracts will take reasonable steps to ensure that subrecipient Investigators comply with this Addendum by incorporating in WHOI's written agreement with the subrecipient, terms that establish whether WHOI's financial conflicts of interest policy or that of the subrecipient will apply to the subrecipient's Investigators.

If the subrecipient's policy applies, the written agreement will specify the time period(s) for the subrecipient to report all identified FCOIs initially and annually thereafter to WHOI. The time period(s)

will be sufficient to allow WHOI to provide FCOI reports to the PHS agency prior to the expenditure of funds and within 60 days of finding any additional FCOI.

If WHOI's policy, as awardee, applies, the subrecipient Investigators will disclose all SFIs that are directly related to the subrecipient's work for WHOI. The written agreement with the subrecipient will specify the time period for the sub-recipient to submit all Investigator disclosures of SFI to WHOI. This time period will be sufficient for WHOI to comply timely with its review, management and reporting obligations to the PHS agency before expenditure of funds and within 60 days of finding any additional FCOI.

G. Reporting Financial Conflict Of Interest To PHS agency

The DoR will report to the appropriate PHS agency a FCOI report if a significant FCOI is found for any key investigator. Report ("FCOI Report") to PHS will contain all the information required under federal regulations at 42 CFR, Part 50, Subpart F, § 50.605(b)(3) and 45 CFR, Part 94, § 94.5(b)(3), as applicable. Reports that must be filed are

- Prior to the expenditure of any funds under a NIH-funded research project.
 - i. Whenever an Investigator does not disclose a significant FCOI.
 - ii. Whenever WHOI does not review a disclosed SFI and then determines a FCOI exists.
 - iii. If a significant FCOI is eliminated prior to expenditure of NIH-awarded funds, no report is required.
- During an ongoing NIH-Funded Research Project, a report that ensures the implementation of a management plan.
 - i. Within 60 days of identifying a new SFI of a current Investigator
 - ii. Within 60 days of determining that a SFI exists for a newly participating Investigator's on the project.
 - iii. Within 60 days of determining that an Investigator did not disclose a previously existing SFI, or the SFI was not reviewed, WHOI must implement a management plan and submit a report to NIH. In accordance with 42 CFR, Part 50, Subpart F, § 50.605(a)(3)(iii) and 45 CFR, Part 94, § 94.5a)(3)(iii). Within 120 days, a Retrospective review must be conducted and a report on this review submitted to NIH.
- Annual FCOI Report.

For the duration of any project period (including extensions), WHOI will provide an annual FCOI report that addresses, the status of any significant FCOI interest and any changes to the management plan or an explanation of why a FCOI no longer exists. Key elements that must be included in the FCOI report to NIH are

 - i. Project number;
 - ii. PI or Contact PI if a multiple PI model is used;
 - iii. Name of the Investigator with the Financial Conflict of Interest;
 - iv. Name of the entity with which the Investigator has a Financial Conflict of Interest;
 - v. Nature of the significant financial interest (e.g., equity, consulting fee, honorarium);
 - vi. Value of the financial interest (dollar ranges are permissible: \$0-\$4,999; \$5,000- \$9,999; \$10,000-\$19,999; amounts between \$20,000-\$100,000 by increments of \$20,000; amounts above \$100,000 by increments of \$50,000), or a statement that the interest

- is one whose value cannot be readily determined through reference to public prices or other reasonable measures of fair market value;
- vii. A description of how the significant financial interest relates to the PHS-funded research and why the Institution determined that the significant financial interest conflicts with such research;
 - viii. A description of the key elements of the Institution's management plan, including:
 - a. Role and principal duties of the conflicted Investigator in the research project;
 - b. Conditions of the management plan
 - c. How the management plan is designed to safeguard objectivity in the research project;
 - d. Confirmation of the Investigator's agreement to the management plan;
 - e. How the management plan will be monitored to ensure Investigator compliance;
 - f. Other information as needed.
- Upon request of the PHS agency
The DoR will make information available to the PHS relating to any Investigator disclosure of financial interests and the Institution's review of, and response to, such disclosure, whether or not the disclosure resulted in the Institution's determination of a financial conflict of interest.

H. Record Retention

The Investigator's Department, through the Department Administrator, will retain all disclosure forms (including the review and response of disclosures regardless of a FCOI finding), conflict management plans, and related documents (e.g., written requests by any requestor for SFI information and WHOI's responses) for a period of three (3) years from the date the final expenditure report is submitted to the PHS or to the prime PHS awardee. If any litigation, claim, financial management review, or audit is started before the expiration of the three year period, the records shall be retained until all litigation, claims or audit findings involving the records have been resolved and final action taken.

I. Confidentiality

To the extent permitted by law, all disclosure forms, conflict management plans, and related information will be confidential. WHOI may be required to make such information available to the PHS Awarding Component and/or HHS, to a requestor of information concerning FCOI related to PHS funding or to the primary entity who made the funding available to the Institution, if requested or required. If WHOI is requested to provide disclosure forms, conflict management plans, and related information to an outside entity, the Investigator will be informed of this disclosure.

J. Public Accessibility

This Addendum is publicly available on Woods Hole Oceanographic website (<http://www.who.edu/DoR/research-conduct/public-health-service-coi-regulations>).

Prior to the expenditure of funds, WHOI will provide to any requestor within five (5) business days of a written request to the DoR's Office, information concerning any SFI that meets the following criteria:

- The SFI was disclosed and is still held by the senior and key personnel;

- A determination has been made by WHOI that the SFI is related to the PHS-funded research; and
- A determination has been made by WHOI that the SFI is a FCOI.

The information to be made available shall be consistent with the requirements of the PHS regulation specified in 42 CFR, Part 50, Subpart F, §50.605(a)(5)(ii) and 45 CFR, Part 94, § 94.5(a)(5)(ii.)

WHOI shall make available the following information in a written response.

- Project number
- The PI or contact PI if a multiple PI model is used
- Name of Investigator with the FCOI
- Name of entity with which the Investigator has a FCOI
- Nature of the SFI (e.g. , equity, consulting fee, travel reimbursement)
- Value of the financial interest (dollar ranges are allowed: \$0 = \$4,999, \$5,000- \$9,999, \$10,000-\$19,999; amounts between \$20,000-\$100,000 by increments of \$20,000; amounts above \$100,000 by increments of \$50,000) or a statement that the interest is one whose value cannot be readily determined through reference to public prices or other reasonable measure of fair market value.

WHOI shall note in its written response that the information provided is current as of the date of the correspondence and is subject to updates on at least an annual basis and with 60 days of identification of new FCOI which should be requested subsequently by the requestor.

K. Submission of the Research Application (Proposals To PHS Agency)

WHOI will certify in the application to PHS agency that WHOI has an effective, implemented policy and is in full compliance with the federal regulations at 42 CFR Part 50 and 45 CFR Part 94, as specifically enumerated in 42 CFR §50.604(k)(1)-(5) and 45 CFR §94.4(k) (1)-(5).

The Institution certifies that it

- has an up-to-date, written, and enforced administrative process to identify and manage FCOI;
- shall promote and enforce Investigator compliance with the federal regulations including the disclosure of SFI;
- shall manage FCOI and provide initial and ongoing FCOI reports to the PHS- funding agency;
- agrees to promptly provide information to HHS on the disclosure of the SFI and the Institution's review of and response to such disclosure whether or not the disclosure resulted in the Institution's determination of a FCOI.

RESPONSIBLE PARTIES

The Woods Hole Oceanographic Institution Director of Research is responsible for overseeing implementation of and ensuring compliance with this Addendum. The COI Review Committee is responsible for supporting implementation and compliance. This Addendum implements the requirements of 42 CFR 50 Subpart F and 45 CFR 94; where there are substantive differences between this policy and the requirements, the requirements shall take precedence.

RELATED POLICIES AND REFERENCES

WHOI Policies

WHOI Conflicts of Interest Policy

<http://www.who.edu/DoR/page.do?pid=30035&tid=3622&cid=30326>

WHOI Conflicts of Interest Policy for Public Health Service Agency Research

<http://www.who.edu/DoR/research-conduct/public-health-service-coi-regulations>

WHOI Patent Agreement and Process

<http://www.who.edu/filesserver.do?id=33386&pt=10&p=25012>

<http://www.who.edu/filesserver.do?id=47524&pt=2&p=41987>

Training

2011 Regulation FCOI Tutorial

<http://grants.nih.gov/grants/policy/coi/tutorial2011/fcoi.htm>

NIH References and Sources for this Addendum

Financial Conflict of Interest Web Page (<http://grants.nih.gov/grants/policy/coi/>)

Frequently Asked Questions (http://grants.nih.gov/grants/policy/coi/coi_faqs.htm)

Responsibility of Applicants for Promoting Objectivity in Research. ([42 C.F.R. Part 50, Subpart F](#))

Responsible Prospective Contractors. ([45 C.F.R. Part 94](#))

Financial Conflict of Interest FCOI Requirement and Demo Webinar 14 Aug 2012

(<http://videocast.nih.gov/summary.asp?live=10752>)

Federal Register Notice (08/25/2011) (http://grants.nih.gov/grants/policy/coi/fcoi_final_rule.pdf)

Federal Demonstration Partnership Model Financial Conflict of Interest Policy

(http://sites.nationalacademies.org/PGA/fdp/PGA_061001)

This Addendum is effective starting December 31, 2012.
