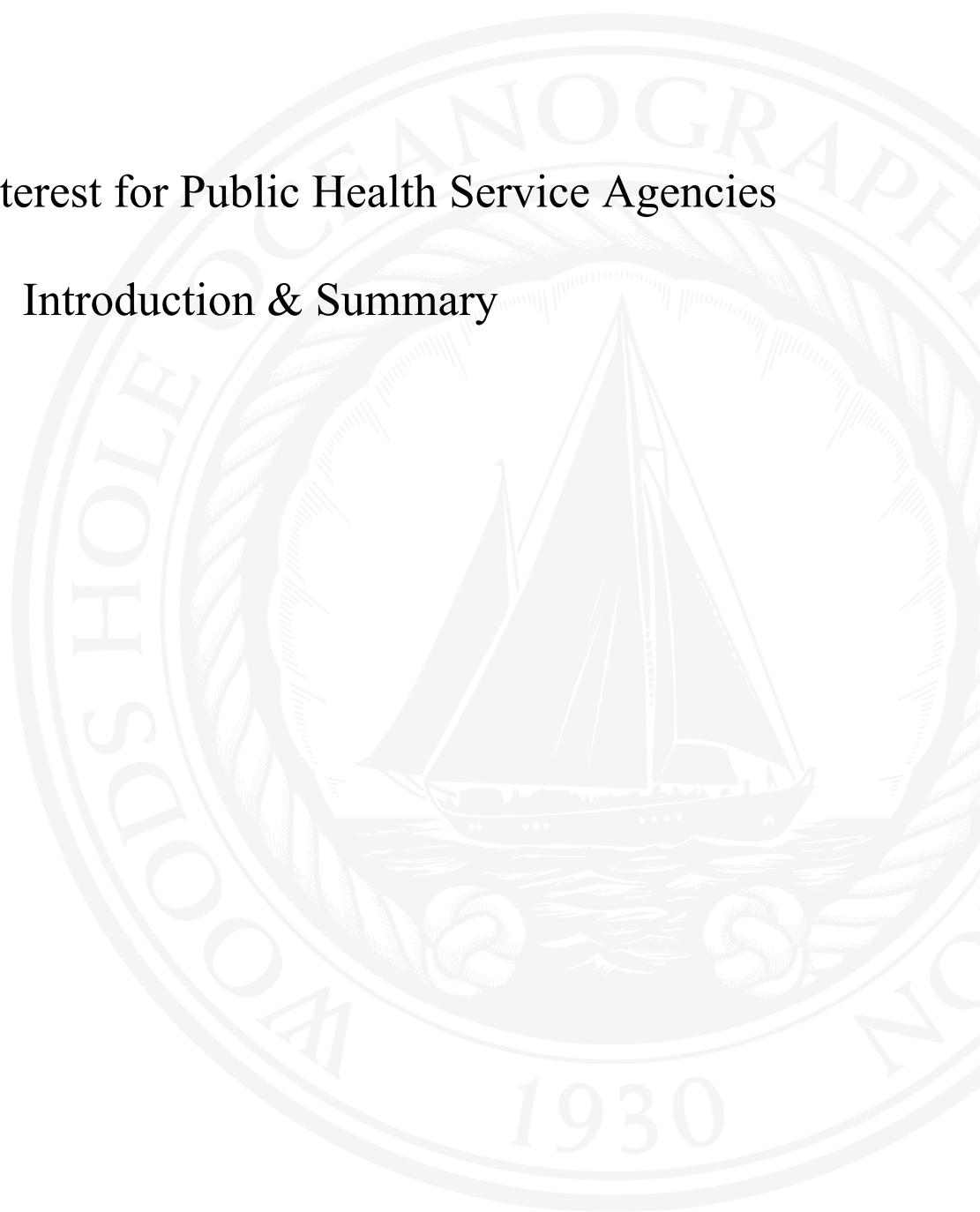


Conflict of Interest for Public Health Service Agencies

Introduction & Summary



Conflict of Interest for Public Health Service Agencies (NIH, CDC, FDA)

Researchers, who are funded by a [Public Health Services Agency](#) (PHS) (see 42 C.F.R. §50.603) must comply with detailed, strict financial conflict of interest [regulations](#). The Department of Health and Human Services enacted the regulations in 2011 to promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct, and reporting of research funded under PHS grants, cooperative agreements, or contracts will be free from bias resulting from Investigator financial conflicts of interest.

The PHS agencies are (1) the Agency for Healthcare Research and Quality (AHRQ), (2) the Agency for Toxic Substances and Disease Registry (ATSDR), (3) the Centers for Disease Control and Prevention (CDC), (4) the Food and Drug Administration (FDA), (5) the Health Resources and Services Administration (HRSA), (6) the Indian Health Service (IHS), (7) the National Institutes of Health (NIH), and (8) the Substance Abuse and Mental Health Services Administration (SAMHSA).

The [financial conflict of interest \(FCOI\) regulations](#) are applicable to each Institution that is applying for, or that receives, PHS research funding by means of a grant, cooperative agreement, or contract and, through WHOI's implementation of these regulations, *applies to every project director or principal investigator and any other person, regardless of title or position, who is involved in the design, conduct or reporting of the PHS research project, or is proposed for such funding, which may include, for example, collaborators or consultants.*

WHOI's [COI/COC Policy](#) and [Addendum to COI for PHS research](#) incorporate the standards and requirements of the regulations in mandatory disclosures. WHOI's COI/COC Disclosure System incorporates all disclosure requirements and elements the regulations establish. Complete disclosure made in compliance with these policies and entered into WHOI's COI/COC Disclosure System enables WHOI and Investigators to meet the responsibilities imposed under the regulations. Elements of the regulations implemented and required under WHOI's policies include, among others:

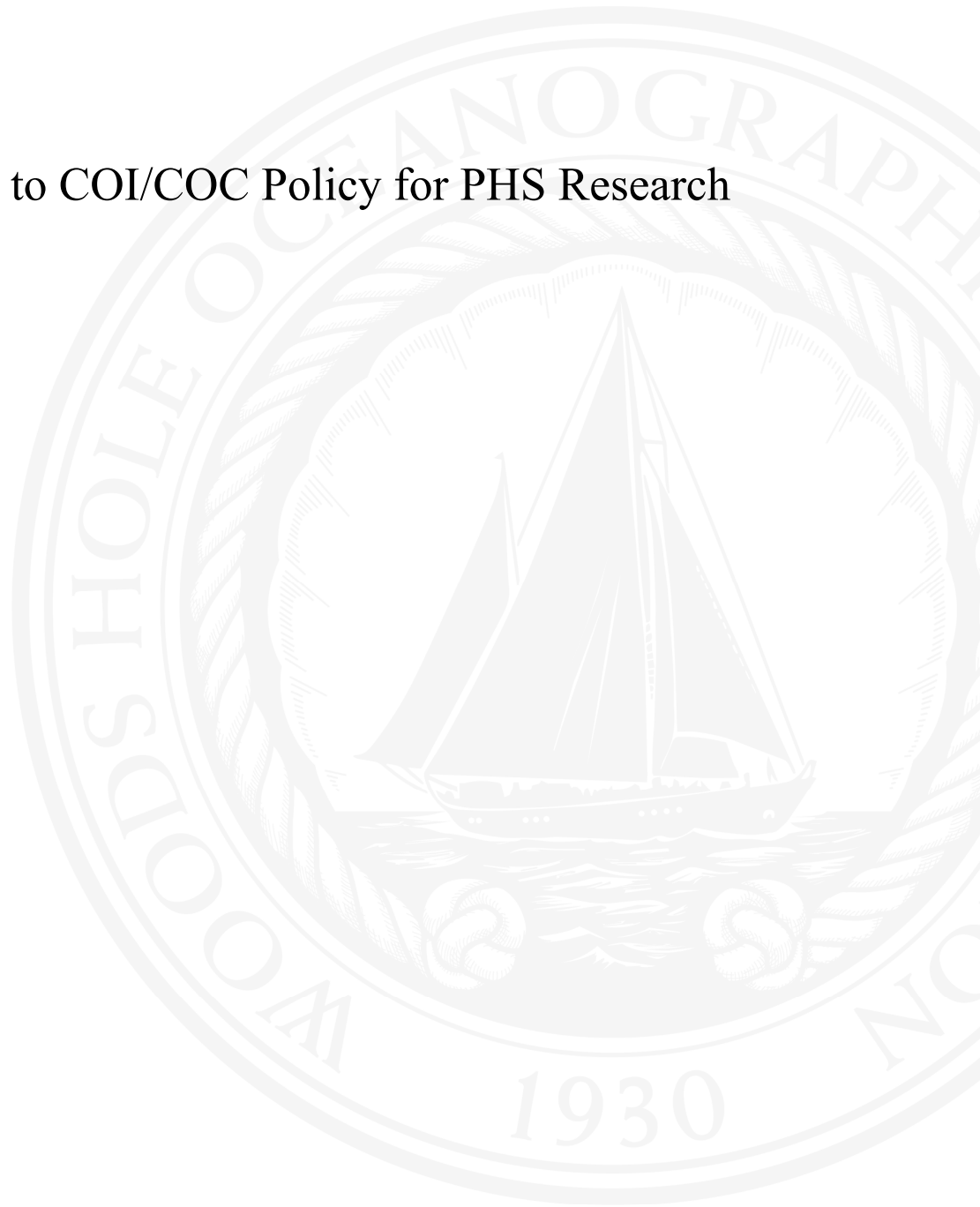
- Mandatory conflict of interest training and periodic renewal.
- Broad mandatory disclosure of all financial interests that relate to an individual's institutional responsibilities, including remuneration from nonprofit entities and sponsored travel.
- A threshold of \$5,000 for "financial interests" as defined in WHOI's COI/COC Policy and policy addendum, "[WHOI Addendum to COI for PHS research \(pdf\)](#)".
- Prior to submitting each PHS proposal, disclose the Investigator's (and Close Relatives') financial interests and update the disclosure annually or within 30 days of changes.
- Prior to expenditure of any funds under a PHS-funded research project, WHOI reviews and manages with a management plan as necessary any financial conflict of interest and

- reports any financial conflict of interest and the associated management plan to the PHS agency.
- Identification, review, management, and reporting to the PHS agency of any financial conflict of interest not timely disclosed or not timely reviewed, managed, and reported.



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Addendum to COI/COC Policy for PHS Research



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)

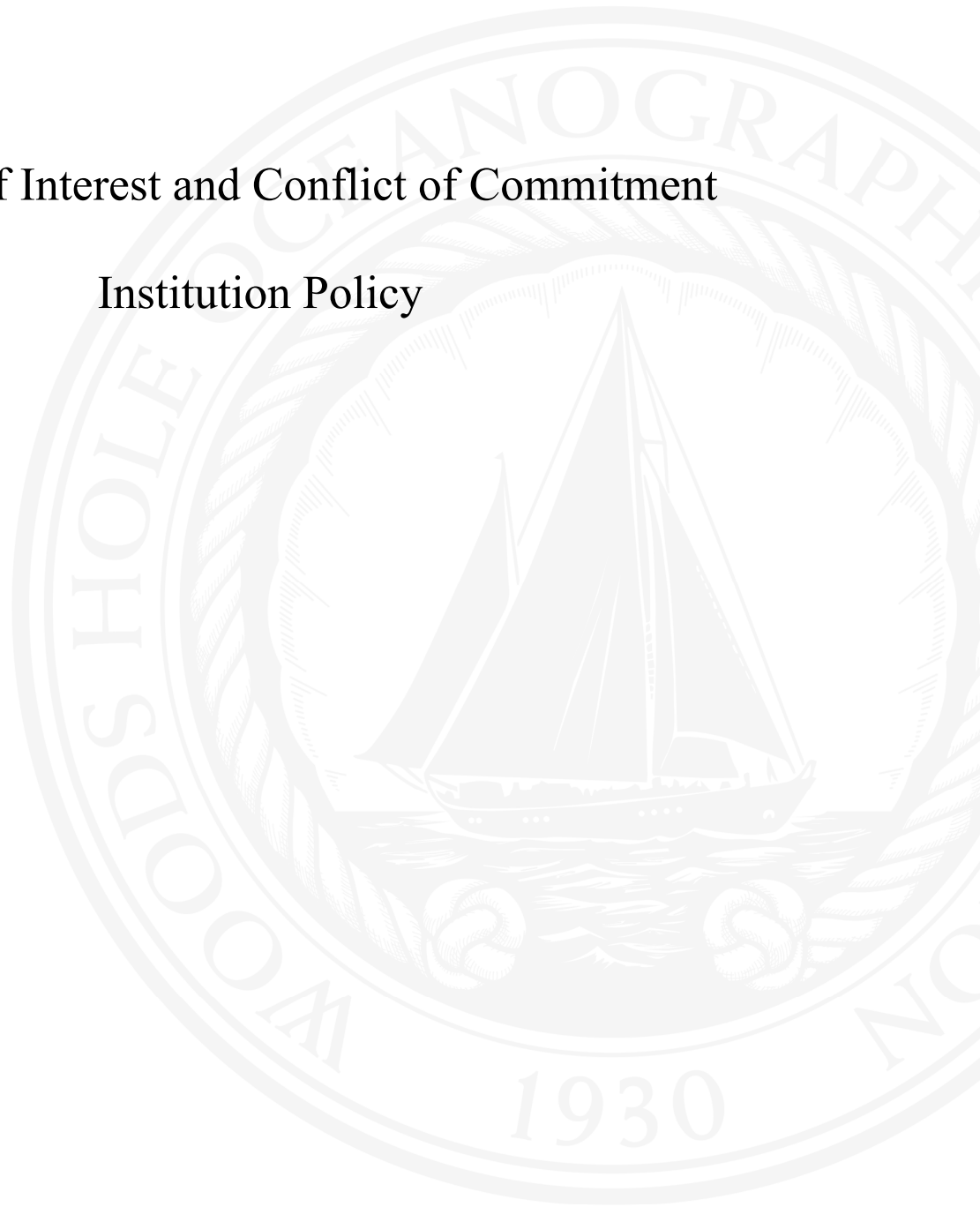
Federal Demonstration Partnership Model Financial Conflict of Interest Policy

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

This Addendum is effective starting December 31, 2012.

Conflict of Interest and Conflict of Commitment

Institution Policy



Institution Policy: Conflict of Interest and Conflict of Commitment

Policy Information

- **Issue Date:** December 10, 1997
- **Revision Date:** September 22, 2020
- **Primary Contact:** Research Administrator
- **Senior Administration:** Deputy Director and Vice President for Research; Vice President for Business and Legal Affairs, General Counsel
- **Responsible Office:** Deputy Director and Vice President for Research; Vice President for Business and Legal Affairs, General Counsel

Policy Statement

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CONFLICT OF INTEREST AND CONFLICT OF COMMITMENT POLICY

In order to promote and protect academic freedom, and the integrity and the mission of the Institution, this policy is implemented to provide transparency and to ensure the resolution of any real, potential, or apparent COI or COC. All Individuals have an obligation to avoid conflict, or the appearance of conflict, between their personal interests and the interests of WHOI and to avoid any situation that affects, or potentially could affect, his or her independent, unbiased judgment in the discharge of his or her duties. COIs and COCs can arise naturally from engagement with the world external to the Institution, and the mere existence of a COI or COC does not necessarily imply wrongdoing. However, both actual conflicts and the appearance of conflicts can be harmful to the Institution, its mission, and to the Individual involved.

Common sense and scientific integrity must prevail in the interpretation of these policies. If an independent observer might reasonably question whether the Individual's professional actions or decisions are determined by considerations of personal financial gain, the relationship should be disclosed to WHOI, as well as to any other parties, during presentations, in publications, in grant or contract proposal process, or other venues. Disclosure to WHOI does not eliminate the need for Individuals to also disclose to any other party, including the general public, any potential conflicts of interest in order to ensure transparency and scientific integrity. WHOI may be required, by law or by conditions imposed by a sponsor, to report a COI and also any failure to report a COI, to the affected project sponsors.

A. Conflict of Interest

WHOI is an institution of public trust; Individuals must respect that status and conduct their affairs in ways that will not compromise the integrity of the institution or that trust. A COI occurs when there is a divergence between an Individual's private interests and professional obligations to WHOI such that an independent observer might reasonably question whether the Individual's professional actions or decisions are determined by considerations of personal Financial Interest. Further, a COI may exist if an external Organization attempts to influence an Individual's or the Institution's work or direct WHOI resources. A COI depends on the situation, and not on the character or actions of the Individual. There are four major categories of conflicts:

1. Financial (e.g., employee or close relative ownership in entities involved with WHOI or affected by WHOI projects, hiring vendors or independent contractors that are Close Relatives).
2. Science (e.g., receiving industry funding/or doing consulting work with an external Organization related to an Individual's research, experience, training, role or responsibilities at WHOI).
3. Mission (e.g., funding from organizations in conflict with our mission).
4. Reputational (e.g., greenwashing, or conveying a false impression or providing misleading information about how a company's products/service are environmentally sound).

Individuals should conduct their affairs so as to avoid or minimize COI, and must respond appropriately when COIs arise. As detailed in the Procedures section, all COIs must be disclosed to WHOI annually on the Conflict Disclosure Form and to other third parties as circumstances warrant. The duty of disclosure is ongoing and continuing, and if a new conflict of interest emerges during the year, disclosure must be made within 30 days. Disclosure does not "cure" a COI – conflicts will be reviewed as detailed in the Procedures section to determine if they must be eliminated or may be managed via a Conflict Management Plan.

Further, no Individual may participate in the selection, award, or administration of a contract supported by a Federal award if he or she has a real or apparent conflict of interest. Such a conflict of interest would arise when the Individual, a Close Relative, or an organization which employs or is about to employ any of the parties indicated herein, has a Financial Interest or other interest in or a tangible personal benefit from a firm considered for a contract. The Individual must neither solicit nor accept gratuities, favors, or anything of monetary value from contractors or parties to subcontracts.

Acceptance of a gift or other thing of value from a vendor working (or seeking to work) on a grant or contract funded by the Federal government is also a prohibited COI by federal law. Consistent with avoidance of COI, Individuals and their Close Relatives are prohibited from soliciting any personal gift, gratuity, favor, service, discount or other benefit (collectively, a "gift") from individuals or companies seeking any advantageous action by, or relationship with, the Institution. A gift valued in excess of \$50 or of undetermined value, unless employed for an Institution purpose or shared widely within the Institution, must be declined or returned immediately. Multiple gifts from a single source in any calendar year are prohibited. Employees are prohibited from accepting gifts of money or their equivalent, regardless of the amount, at any time. Gifts of promotional items without significant value that are routinely distributed by vendors to clients, and courtesy copies of professional printed matter, may be accepted.

However, the following normally are not considered COI and are allowed in the following circumstances:

- (1) Gifts, gratuities, favors, entertainments, loans, or any other thing of monetary value received on account of close family or personal relationships when the circumstances make it clear that it is that relationship rather than the business of the persons concerned which is the motivating factor;
- (2) Acceptance of loans from banks or other financial institutions on customary terms to finance proper and usual activities of employees, such as home mortgage loans;
- (3) Acceptance of unsolicited advertising or promotional material, such as pens, pencils, note pads, calendars, and other items of nominal intrinsic value;
- (4) Acceptance of rates and discounts offered to [employees](#) as a class;
- (5) Acceptance of food and refreshments of nominal value on infrequent occasions in the ordinary course of a luncheon or dinner meeting or other meeting or on an inspection tour where an [employee](#) may properly be in attendance;
- (6) Gifts to the Institution as a whole, not to an employee, agent or officer of the Institution, of minimal or nominal value (such as gifts to WHOI raffles from vendors).

B. Conflict of Commitment

Individuals working half-time or more at WHOI owe their primary professional allegiance to WHOI, and their primary commitment of time and intellectual energies should be to the education and research mission of the institution. Even with such understandings in place, however, attempts of WHOI scientists, engineers, and others to balance WHOI responsibilities with external activities-- such as consulting, public service or pro bono work--can result in conflicts regarding allocation of time and energies. Conflicts of commitment usually involve issues of time allocation. Whenever an Individual's

professional loyalty is not to WHOI, a conflict of commitment can exist. If a situation that raises questions about a possible conflict of commitment arises, Individuals should disclose and discuss the situation with their Department Chair or the Deputy Director and Vice President for Research (DDVPR).

C. Additional Provisions

Individuals may not use WHOI resources, including facilities, staff, students or other trainees, equipment, or confidential information, as part of their external consulting or business activities or for any other purposes that are unrelated to the education, research, scholarship, and public service missions of WHOI without prior approval from ACECS. Any COIs must be eliminated or managed through an approved Conflict Management Plan.

Individuals working half-time or more at WHOI must not allow other activities to detract from their primary allegiance to WHOI. For example, a WHOI PI must not have significant external Managerial Roles or act as a PI on sponsored projects that could be conducted at WHOI but instead are submitted and managed through another institution (excluding such agreements as WHOI-managed sub-awards or collaborations).

Failure to adhere fully to the provisions on this policy could lead to actions under the WHOI Investigations, Progressive Discipline, and/or Termination policies.

OUTSIDE ACTIVITIES (EXTERNAL ORGANIZATIONS AND START-UPS)

In certain situations, it is appropriate for Individuals to have relationships with an external Organization (including as consultants or in WHOI Start-ups) that may be related to the Individual's experience, training, role and responsibilities at WHOI, as determined solely by WHOI. In these cases, the Individual is required to:

- Separate WHOI duties from personal Financial Interests in the company.
- Separate and clearly distinguish on-going Institution research from external Organization responsibilities or work being conducted.
- For Individuals working half-time or more at WHOI, receive permission from ACECS to consult for the external Organization or be employed in a non-managerial role for any amount of time if related to the Individual's experience, training, role and responsibilities at WHOI. (An Individual must receive permission from ACECS if consulting or employment is not related to the Individual's experience, training, role and responsibilities at WHOI and is in excess of 80 hours per year).
- For Individuals working half-time or more at WHOI, refrain from taking Managerial Roles
- (except as noted below with Start-ups).
- Make clear that WHOI is the default owner of intellectual property, and that Individuals cannot enter into any agreement that creates copyright or patent obligations that conflict with WHOI's Intellectual Property Policy or an Individual's agreement to assign their rights to WHOI.
- Seek approval in advance from ACECS, before agreeing to a position on an external Organization's board.

Further, no Individual may:

- Negotiate with WHOI on behalf of the Organization, or vice versa.
- Involve WHOI staff in activities at the Organization without prior approval from ACECS.
- Allow Organization personnel to be affiliated with the Institution.
- Involve Organization personnel in WHOI research without prior approval from ACECS.
- Involve WHOI employees, students or post-docs for whom the Individual has supervisory responsibility in company business or research without prior approval from ACECS, and avoid situations in which any WHOI employee might feel expected to be involved.

No external Organization, including any Start-up, may use any WHOI facility, property, or equipment without a Facility Use Agreement in place (at fair market value) and approval by ACECS.

WHOI Start-ups

WHOI has a proud history of entrepreneurial activity and is supportive of its entrepreneurs, keeping in mind that WHOI is foremost an institution of public trust, with a requirement to maintain openness in research. Entrepreneurial activity must be balanced by careful review of the proposed relationships, which may or may not be allowed, and which may require active management to assure openness in research and education and a clear understanding about how conflicts of interest, and WHOI's intellectual property, are to be managed. WHOI is committed to avoiding either perceived or actual conflict issues with respect to Start-ups, which are companies (however organized) where the original intellectual property originates from within WHOI, and where one or more WHOI individuals is a founder and has a Financial Interest in the company, and may have an influential role in determining the direction of the company. Both WHOI and its science and engineering staff have responsibilities to optimize technology transfer and mitigate conflicts of interest when licensing WHOI intellectual property to a Start-up.

In addition to the permissions and prohibitions listed above, Individuals working on Start-ups shall:

- Refrain from involving WHOI students or post-docs in company activities (if a student/post-doc asks to take a leave of absence to participate in the company, refer the individual to ACECS for review of the request and independent advice).
- Refrain from applying for or receiving internal WHOI funds, including salary support from Investment in Science Program (ISP), Independent Research and Development (IR&D), or cost share if the Individual has a Managerial Role with the Start-up without prior ACECS approval.
- Refrain from being a subawardee on any grant, contract, or other vehicle without prior ACECS
- approval.
- Propose a Conflict Management Plan (CMP) and receive approval from ACECS before engaging in any work related to the Start-up, including before engaging in any Management Role or taking any role or title (e.g., CTO) suggesting management responsibility. Although WHOI discourages the practice, in some circumstances with Start-ups, an Individual may have a Managerial Role if he or she is approved by ACECS after submitting a CMP. The CMP must be updated and approved annually by ACECS.

- Disclose this affiliation and any apparent or actual conflict in any situation where it may not be clear on whose behalf the Individual is operating.

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Definitions & Responsibilities

These definitions apply to these terms as they are used in this policy.

| | |
|---------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Advisory Committee on Ethics, Conflicts, and Security (ACECS) | WHOI's Advisory Committee on Ethics, Conflicts, and Security (ACECS) promotes the principles of ethical research, the protection of national security interests, and their impact on WHOI's mission and successful operation. As such, ACECS provides guidance to the WHOI community in the assessment and oversight of research ethics, conflicts of interest or commitment, intellectual property, and security in research and development projects at WHOI. |
| Conflict of Commitment (COC) | Situations where an Individual's outside activities, however valuable in themselves, interfere or appear to interfere with their obligations to the Institution, colleagues, and students, and/or WHOI's mission. |
| Conflict of Interest (COI) | Situations where an Individual or Close Relative might influence the Institution's business, research, or mission-related activities in ways that could lead to personal gain or give improper advantage to themselves or Close Relatives. |
| Conflict Management Plan (CMP) | An affirmative plan necessary if deemed so by ACECS to mitigate disclosed conflict if the Individual does not eliminate the conflict. |
| Facility Use Agreement | Form to be submitted by an Individual that intends to use any WHOI facility, property or equipment for an external Organization or for the purposes of a Start-up company. |
| Financial Interest | Anything of monetary value whether or not the value is readily ascertainable. These include serving as employee, consultant, contractor or board member; being entitled to receive income, equity interests (e.g., stock or stock options), royalties, or payments (e.g., salary, consulting fees, honoraria, paid authorship fees); having an investment or ownership interest in excess of \$5,000; intellectual property rights and interests (e.g., patents, copyrights, royalties) from a company |

valued in excess of \$5,000 when aggregated in the 12 months preceding the disclosure.

Exemptions from Financial Interest include salaries, royalties, or other income paid by WHOI to the Individual if the Individual is currently employed or appointed by WHOI; Standard Honoraria; and income from investment vehicles, such as mutual funds and retirement accounts, as long as the Individual (or the Individual's Close Relative) does not directly control the investment decisions made in these vehicles are exempted from being Financial Interests.

Individual

All personnel at WHOI including the Scientific and Technical Staff, Trustees, Administrative Staff and all other employees, students (other than MIT-WHOI JP students), post-doctoral fellows/ investigators/ scholars, and anyone who has a WHOI appointment including visitors, guests, Emeriti, and adjuncts.

Industry-Sponsored Research Investigator

Research funded by an external industry Organization. The principal investigator (PI), co-principal investigator, or any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research or educational activities funded or proposed for funding.

Managerial Role

Role within an Organization that includes but is not limited to responsibilities of planning, organizing, leading, administrating, and controlling the organization as a whole or in part. The person in a Managerial Role often has supervisor duties and may have direct reports. Some such roles could be titled President, CEO, CTO, Department Chair, Center Director, Program Manager, Project Manager, Chief Research Officer, Lab Manager, etc.

Organization

Any entity, or company, publicly or privately held, including Institution of Higher Learning or institute affiliated with Institutions of Higher Learning, Corporation, Federal, State or Local Government Agency, Foundation, non-profit or not-for-profit entities.

Standard Honorarium

Income from seminars, lectures, teaching engagements, service on advisory committees or review panels that are reimbursed or sponsored by an Organization not to exceed \$1,000. Acceptance of honoraria in excess of \$1,000 requires permission from the Deputy Director and Vice President for Research.

Start-up Company (Start-up)

A company, however organized, where the original intellectual property originates from within WHOI, and where one or more WHOI Individuals is/are a founder and has a Financial Interest in the company, and may have an influential role in determining the direction of the company.

| | |
|------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Disclosure of COI and COC | <p>Disclosure and consultation continue to be the best means for avoiding conflicts of interest. COI and COC situations are often complex and judgments may differ on whether or not a conflict, in fact, exists.</p> <p>Disclosure to WHOI does not eliminate the need for Individuals to also disclose to an agency, sponsor, or any other party, including the general public, any potential conflicts of interest in order to ensure transparency and scientific integrity. For example, Investigators who receive funding from Public Health Service must also report Financial Interest using the Addendum Financial Interest Report.</p> |
| Who must disclose COI and COC? | All Individuals, as defined above, who have an apparent, potential, or real COI or COC. |
| Who does not need to submit a Disclosure form? | Only MIT faculty with a WHOI faculty appointment and Guest Investigators and Visiting Scholars, each of whom must have received less than \$5,000 annually from WHOI, and MIT- WHOI JP students, are excepted from this policy. The DDVPR in consultation with the General Counsel may, at their discretion, choose to exclude certain affiliates from this Policy. |
| What must be disclosed? | <p>Individuals must disclose to WHOI whether they or a Close Relative have a COI or COC, including any external professional activities that relate to the Individual's experience, training, role and responsibilities at WHOI, or any external professional activities not related to the Individual's experience, training, role and responsibilities that total more than 80 hours per year, or any Financial Interest in an external Organization that would reasonably appear to be related to their institutional responsibilities. Disclosures of such interests are also required when the Individual is involved in a specific transaction, including gifts; sponsored projects; technology licensing arrangements; material transfer and collaboration agreements; and certain procurements (e.g., sole source or from a privately-held company). When in doubt, disclose.</p> <p><i>Disclosure to WHOI does not obviate disclosure to any other party, including public disclosure. If an independent observer might reasonably question whether the Individual's professional actions or decisions are determined by considerations of personal financial gain, the relationship should be disclosed including during presentations, in publications, or other venues.</i></p> |
| When to disclose? | <p>The Conflict Disclosure form is to be submitted online not later than January 31st for the previous year's activities. If no activity has been performed, this should be so indicated on the Conflict Disclosure Form.</p> <p>If a conflict arises between annual reporting, the Disclosure Report form must be updated and the COI reported within 30 days. It is the duty of the Individual to keep the Disclosure Report form current and to update the form as needed during the year. Any new employee or Individual newly affiliated with WHOI will fill out the Conflict Disclosure form at check-in or with their Department. A PI must disclose to the Department Chair or Dept Administrator any potential COI or COC during the creation of a proposal or purchase order. This is in addition to yearly COI and COC disclosure. The Department Chair and Dept Administrator should send this disclosure to ACECS for review. ACECS will make recommendations for management of any potential conflicts. The PI must disclose to the Department early in the proposal process and prior to the routing of the proposal for submission. This to assure that submission is not denied due to an undisclosed COI that has not been reviewed by ACECS.</p> |

How are COIs and COCs reviewed?

Supervisors or Department Chairs/Administrators should review the conflict first through Conflict Disclosure Forms, and submit their mitigation plan (e.g., Conflict Management Plan) along with a request for review by ACECS to ACECS@whoi.edu. PIs and other staff with any actual or perceived conflicts of interest should consult with their department chair for advice before submitting to ACECS. Examples of activities to review include:

- All Industry-Sponsored Research or projects;
- Any compensated commitments of a professional or business nature for any amount of time that relates to work at WHOI or work which exceeds 80 hours that does not relate to work performed at WHOI;
- Any proposed consulting arrangements with a company for any amount of time that relates in any way to the work performed at WHOI;
- Opportunities that have a commercial or corporate connection, including technology licensing and transfer;
- Corporate sponsorships, giveaways, partnerships, perceived or actual endorsements of any kind, or other activities;
- Advancement or development opportunities that involve partnerships with any external organization or the use of WHOI's name, logo, or brand;
- All apparent or real COI or COC brought to its attention by a Department Chair or Administrator, or a department in the course of doing business related to WHOI;
- Formal conflict management plans (CMPs) before they go to the DDVPR for final approval.

The goal of the review is to determine what conditions or restrictions, if any, should be imposed to manage, reduce, or eliminate any conflict to ensure that the Institution permits and promotes activities that are aligned with WHOI's mission and values, and maintains the integrity and independence of the Institution and its people. In the event that a COI or COC determination is made by ACECS, it will be reported in writing to the Office of General Counsel, who will advise the DDVPR. The DDVPR makes the determination in writing to the affected employee(s), with a copy to the Director. In addition, ACECS will inform any and all appropriate Institution offices and departments of this action, along with any restrictions and/or conditions that have been imposed as a consequence.

If an Individual elects to appeal the action taken by the DDVPR, the Director will conduct an independent review and his/her determination shall be binding. The Director has the ultimate authority and responsibility to determine when the foregoing policy applies and what steps, including procedural enforcement and sanctions, should be taken to correct a situation deemed not in the best interests of the Institution. WHOI may be required, by law or by conditions imposed by a sponsor, to report a COI and also any failure to report a COI, to the affected project sponsors.

When does Conflict Management and CMP occur?

Some conflicts must be eliminated, but often the Institution can work with the Individual through ACECS to manage a conflict or the appearance of a conflict so that the activity can continue in a way that minimizes the possibility of bias and preserves objectivity. Proper management of a conflict depends on full and prompt disclosure. Furthermore, WHOI recognizes that while an Individual's primary professional commitment is to the Institution, consulting and other forms of independent work can be accepted activities.

If determined by ACECS, an Employee can be required to submit a CMP that must include, at a minimum,:

- Full description of the external relationship(s);
- Identification of the area(s) of potential conflict of interest;
- Management strategies to guard against the escalation of a true conflict of interest (firewall, create an independent review, monitor, or oversight committee, and/or disclosures to the sponsor agency or funding body).

This may also include monitoring of research by independent reviewers; modification of the research plan; disqualification from participation in the portion of the research that would be affected by Financial Interests; divestiture of Financial Interests; or severance of relationships that create conflicts.

A Conflict Management Plan must be submitted and approved by an Individual's Department Chair or supervisor, and then submitted to ACECS for review and approval. *CMPs must be resubmitted annually for review by ACECS and the Supervisor or Department to determine whether the conflict remains mitigated*

Financial Conflict of Interest Policy for Investigator Receiving Funds from Public Health Service Agencies

In addition to the Conflict Disclosure form to be submitted every year or when there is a change in an Individual's situation, Investigators who are funded by a Public Health Service Agency are required:

- a) to take WHOI COI training every 4 years and be familiar with the WHOI Addendum to COI for PHS research, and
- b) at least yearly, fill out the Addendum Financial Interest Report.

Regulations for PHS differ from WHOI and NSF COI and apply to all investigators who are involved in the design, conduct, or reporting of a PHS research project and applies to new proposal, new award, non-competing renewals and new no-cost extensions. Regulations include:

- Mandatory PHS training least every 4 years. This is the same training as the Institution's COI and COC.
- Broader disclosure requirement of all financial interests that relate to an Individual's institutional responsibilities, including remuneration from non-profit entities and sponsored travel.
- A threshold of \$5,000 annually for "significant financial interests" as defined in the policy addendum "[WHOI Addendum to COI for PHS research](#)".

Prior to submitting Public Health Service (PHS) (e.g.

NIH, FDA, CDC) proposals or to dispersal of funds from PHS award, WHOI is required assure that all training and financial interest reports are up to date and completed, review and manage as necessary any financial conflict of interest, and report financial conflict of interest and management plan to the PHS agency. WHOI is required to have policy and procedures that are in compliance with the PHS regulations.

Failure to comply with the Policy

Failure to comply with this Policy could lead to actions under the WHOI Investigations, Progressive Discipline, and/or Termination policies, and may result in sanctions, including a formal reprimand in an Individual's personnel file, adverse impact on Individual's evaluation and any potential raises, disclosure to federal agencies and/or the public, and termination of Individual's employment or affiliate status.

Forms

[Conflict Disclosure form only for Individuals **without** WHOI email and LDAP password](#)

[Link for Conflict Disclosure form for those Individuals **without** WHOI email and LDAP password.](#) This link will not open the Disclosure form for those individuals with WHOI email and LDAP.

[Conflict Disclosure form](#) for WHOI employees, Emeriti and affiliates **with WHOI email and LDAP**

[Link for Conflict Disclosure form for those Individuals **with** WHOI email and LDAP password.](#)

[Conflict of Interest Training for Individuals **without** WHOI email and LDAP password](#)

[Conflict of Interest training for Individuals **without** WHOI email and LDAP password.](#)

[Conflict of Interest Training for Individuals **with** WHOI email and LDAP password](#)

[Conflict of Interest training for Individuals **with** WHOI email and LDAP password.](#)

Conflict of Interest for Public Health Service Agencies

[Public Health Services Agency financial disclosure and training requirements](#)

Financial Conflict of Interest form (for PHS funded Individuals)

Individuals funded by a Public Health Services Agency (e.g. NIH, CDC) must also submit a [PHS Financial Conflict Interest Form](#) (FCOI) to their Department for forwarding to GCS on a yearly basis.

WHOI COI Addendum for Public Health Services Funded Individuals

WHOI Addendum to WHOI Conflict of interest and Outside Professional Activities Policy Applicable to Public Health Services Funded Investigators.

Facilities Use Agreement

[Contact Office of the General Counsel](#)

Frequently Asked Questions and Examples

| <u>Question</u> | <u>Answer</u> |
|------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| WHO MUST FILL OUT THE ANNUAL DISCLOSURE? | All personnel at WHOI -- including scientific and technical staff, administrative staff and all other employees, post-doctoral fellows/ investigators/ scholars, and anyone with a WHOI appointment including visitors, guests, Emeriti, and adjuncts. Only MIT faculty with a WHOI faculty appointment and Guest Investigators and Visiting Scholars, each of whom must have received less than \$5,000 annually from WHOI, and MIT- WHOI JP students, are excepted from this policy. |
| WHAT MUST BE DISCLOSED? | - Any real or apparent Conflicts of Interest (COI) or Conflicts of Commitment (COC). |
| WHAT IS A CONFLICT OF INTEREST? | A COI occurs when there is a divergence between an Individual's private interests and professional obligations to WHOI such that an independent observer might reasonably question whether the Individual's actions or decisions are determined by considerations of personal financial gain. COIs can be any outside activity, paid or unpaid, which may benefit you or a Close Relative (e.g., spouse, domestic partner, child, stepchild, parent or sibling) that relates to WHOI, or that relates to your work at WHOI. |

WHAT ARE DIFFERENT TYPES OF COI?

Financial (e.g., ownership in entities involved with WHOI or affected by WHOI projects, hiring vendors or independent contractors that are Close Relatives).

Science (e.g., receiving industry funding/or doing consulting work with industry on research related to work performed at WHOI).

Mission (e.g., funding from organizations in conflict with our mission).

Reputational (e.g., greenwashing, or conveying a false impression or providing misleading information about how a company's products/service are environmentally sound).

WHAT ARE SOME EXAMPLES OF COI and COC?

You or a Close Relative owns, operates, or works at an organization that competes with WHOI, or sells (or could sell) materials or services to WHOI.

You or a Close Relative are on the board at an organization that does business with WHOI, or does similar work to any of the work you do for WHOI.

You or a Close Relative have a consulting agreement with a company that does business with WHOI, or that is in the same field as any of the work you do for WHOI.

You have applied for or accepted any industry-sponsored research (e.g., a chemist doing industry research with an oil company)

You hold a tenured position at another institution while a member of the WHOI scientific staff.

You withhold information emanating from any sponsored research to attain personal gain or profit.

You give access to proprietary Institution information to assist an external organization.

You consult under arrangements that impose obligations in conflict with Institution patent or copyright policy or with obligations to research sponsors. (Individuals must contact the Office of Technology Transfer for assistance with drafting standard form consulting agreements.)

Circumstances in which research or other activities that ordinarily would be carried on within the Institution are conducted elsewhere to the disadvantage of the Institution.

You are paid twice for the same work.

You have interactions with suppliers, contractors or subcontractors, or others doing business with the Institution in any way that may give favor based on personal considerations.

You participate in an activity (research project, conference, teaching program, consulting agreement, etc.) on an individual or outside basis:

- that involves or appears to involve the Institution's resources, logo, or reputation,
- that violates any of the principles governing research supported by funds administered through the Institution, or
- that has the potential to inhibit the free communication of ideas among colleagues or restrict availability or dissemination of the results of research.

HOW DO I DISCLOSE?

(1) Take the COI Training online, then (2) fill out the Conflict Disclosure Form. Do not rely on past Conflict Disclosure Forms when filing out the annual form.

DOES DISCLOSURE "CURE" MY COI?

No. Disclosure is the first step, and then Department Chairs or Supervisors will review and work with ACECS to determine any next steps. Keep in mind that, in addition to the Conflict Disclosure Form to WHOI, you may need to disclose your potential COI to third parties during presentations, in publications, in grant or contract proposal process, or other venues. WHOI is an institution of public trust; Individuals must respect that status and conduct their affairs in ways that will not compromise the integrity of the Institution or that trust.

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Problems or questions about the site, please contact webdev@whoi.edu