

**INTERNATION CENTER FOR RESEARCH ON WOMEN (ICRW)
PHS FUNDED RESEARCH
FINANCIAL CONFLICT OF INTEREST (FCOI) POLICY**

A. INTRODUCTION

The U.S. Department of Health and Human Services (HHS) issued a final rule in the [Federal Register](#) that amends the Public Health Service (PHS) regulations on Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is Sought (42 Code of Federal Regulation (CFR) Part 50, Subpart F) and Responsible Prospective Contractors (45 CFR Part 94) on 25 August 2011.

An Institution applying for or receiving PHS funding from a grant or cooperative agreement must be in compliance with all of the revised regulatory requirements no later than August 24, 2012, and immediately upon making the Institution's Financial Conflict of Interest (FCOI) policy publicly accessible as described in 42 CFR 50.604(a).

B. PURPOSE

The purpose of the policy is to implement the revised PHS regulation, which is in addition to the ICRW general Conflict of Interest (COI) policy. This policy applies to all Investigators, as defined below, who are planning to participate in or who are already participating in PHS funded research.

C. AUTHORITY

The Chief Operating Officer (COO) for ICRW serves as the Institutional Official (IO) and is responsible for ensuring implementation of this policy and has the authority to suspend all relevant activities until a FCOI is resolved or other action deemed appropriate by the IO is implemented. Violation of any part of these policies may also constitute cause for disciplinary or other administrative action pursuant to this policy and in accord with ICRW policies and procedures.

The IO has designated implementation and management of this policy and processes related to this policy as described below to the ICRW Research Compliance Office.

D. DEFINITIONS

Disclosure of significant financial interests means an Investigator's disclosure of significant financial interests to an Institution (42 CFR 50.603).

Financial Interest means anything of monetary value, whether or not the value is readily ascertainable (42 CFR 50.603). For ***Investigators***, financial interest also includes any reimbursed or sponsored travel undertaken by the Investigator and related to his/her institutional responsibilities. This includes travel that is paid on behalf of the Investigator rather than reimbursed, even if the exact monetary value is not readily available. It excludes travel reimbursed or sponsored by U.S. Federal, state or local governmental agencies, U.S. institutions of higher education, research institutes affiliated with institutions of higher education, academic teaching hospitals, and medical centers.

Financial Conflict of Interest (FCOI) means a significant financial interest that could directly and significantly affect the design, conduct or reporting of PHS funded research (42 CFR 50.603).

FCOI report means an Institution's report of a financial conflict of interest to a PHS Awarding Component (42 CR50.603).

HHS means the United States Department of Health and Human Services, and any components of the Department to which the authority involved may be delegated.

Immediate Family means the Investigator's spouse, domestic partner, and any dependent children.

Institution means the International Center for Research on Women Headquarters and all Regional Offices.

Institutional Official (IO) means the individual within the Institution that is responsible for the solicitation and review of disclosures of significant financial interests, including those of the Investigator's immediate family, related to the Investigator's institutional responsibilities. For the purposes of this policy, the Chief Operating Officer (COO) for ICRW.

Institutional responsibilities means the Investigator's responsibilities associated with his or her Institutional appointment or position, such as research, research consultation, teaching, professional practice, institutional committee memberships, and service on panels such as Institutional Review Boards or Data and Safety Monitoring Boards (42 CFR 50.603).

Investigator means the project director or principal Investigator and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research funded by the PHS, or proposed for such funding, which may include, for example, collaborators or consultants (42 CFR 50.603).

Manage means taking action 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 (42 CFR 50.603).

Management Plan means a written document signed by the IO, Investigator, and other appropriate individuals and supervisors outlining the specific steps to be taken to address a Financial Conflict of Interest(s).

Mitigation Report means a report from the Institution to PHS which must be submitted when bias is found during a Retrospective Review.

Public Health Service or PHS means the Public Health Service of the U.S. Department of Health and Human Services, and any components of the PHS to which the authority of the PHS may be delegated. The components of the PHS include, but are not limited to, the Agency for Healthcare Research and Quality (AHRQ), Agency for Toxic Substances and Disease Registry (ATSDR), Centers for Disease Control and Prevention (CDC), Food and Drug Administration (FDA), Health Resources and Services Administration (HRSA), Indian Health Service (IHS), National Institutes of Health (NIH), Substance Abuse and Mental Health Services Administration (SAMHSA).

Research means a systematic investigation, study, or experiment designed to 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). The term includes any such activity for which research 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 (42 CFR 50.603).

Retrospective Review means a compliance review conducted by the Institution of a Financial Conflict of Interest(s) that was not identified or managed in a timely manner.

Senior/key personnel means the Project Director (PD) or Principle Investigator (PI) and any other person identified as senior/key personnel by the Institution in the grant application, progress report, or any other report submitted to the PHS by the Institution (42 CFR 50.603).

Significant Financial Interest means (42 CFR 50.603):

1. A financial interest consisting of one or more of the following interests of the Investigator (and those of the Investigator's spouse and dependent children) that reasonably appears to be related to the Investigator's institutional responsibilities:
 - a. With regard to any **publicly traded entity**, a significant financial interest exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure and the value of any equity interest in the entity as of the date of disclosure, when aggregated, exceeds \$5,000. For purposes of this definition, remuneration includes salary and any payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorship); equity interest includes any stock, stock option, or other ownership interest, as determined through reference to public prices or other reasonable measures of fair market value;
 - b. With regard to any **non-publicly traded entity**, a significant financial interest exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure, when aggregated, exceeds \$5,000, or when the Investigator (or the Investigator's spouse or dependent children) holds any equity interest (e.g., stock, stock option, or other ownership interest); or
 - c. Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.
2. Investigators also must disclose the occurrence of any **reimbursed or sponsored travel** (i.e., that which is paid on behalf of the Investigator and not reimbursed to the Investigator so that the exact monetary value may not be readily available), related to their institutional responsibilities; provided, however, that this disclosure requirement does not apply to travel that is reimbursed or sponsored by a Federal, state, or local government agency, an Institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education. The Institution's FCOI policy will specify the details of this disclosure, which will include, at a minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration. In accordance with the Institution's FCOI policy, the institutional official(s) will determine if further information is needed, including a determination or disclosure of monetary value, in order to determine whether the travel constitutes an FCOI with the PHS funded research.
3. The term **significant financial interest does not include**:

1. Salary, royalties, or other remuneration paid by the Institution to the Investigator if the Investigator is currently employed or otherwise appointed by the Institution, including intellectual property rights assigned to the Institution and agreements to share in royalties related to such rights.
2. Any ownership interest in the Institution held by the Investigator, if the Institution is a commercial or for-profit organization.
3. Income from investment vehicles, such as mutual funds and retirement accounts, as long as the Investigator does not directly control the investment decisions made in these vehicles.
4. Income from seminars, lectures, or teaching engagements sponsored by a Federal, state, or local government agency, an Institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education.
5. Income from service on advisory committees or review panels for a Federal, state, or local government agency, an Institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education.

E. TRAINING REQUIREMENTS

The ICRW's Research Compliance Office is responsible for ensuring that each Investigator is informed about this FCOI policy, disclosure responsibilities, and the Federal Regulations (PHS 42 CFR Part 50, Subpart F and 45 CFR Part 94) in accordance with section F below. Each Investigator must complete training on this Policy and the Federal Regulation prior to engaging in PHS funded research, and at least every four years while engaged in PHS funded research. They must also complete training within a reasonable period of time, as determined by the IO, if this Policy is substantively amended in a manner that affects the requirements of Investigators, or if it is determined that the Investigator has not complied with this Policy or with a Management Plan related to their activities. Training on the Federal Regulation (i.e. PHS Conflict of Interest training) will be provided through the Collaborative Institutional Training Initiative (CITI). Information and training (as necessary) on this Policy is provided by the Research Compliance Office.

F. DISCLOSURE, REVIEW, AND MONITORING REQUIREMENTS:

1. Disclosure:

All Investigators are required to disclose their significant financial interest (SFI), which includes SFI of their immediate family, related to their Institutional responsibilities to the Institution as follows:

- a) ***New Hire Disclosure:*** All Investigators that will participate in PHS funded research must disclose their SFIs to the Institution within 30 days of hire and prior to participation in such research (if on-going at time of hire).
- b) ***Application Disclosure:*** All Investigators must disclose their SFIs to the Institution, at the time of application for PHS funding.
- c) ***Annual Disclosures:*** All Investigators must disclose their SFIs to the Institution, at least annually while participating in PHS funding.
- d) ***Ad hoc Disclosures:*** In addition to annual disclosure, certain situations require ad hoc disclosure. All Investigators must disclose their SFIs to the Institution within 30 days of discovering or acquiring (e.g., through purchase, marriage, or inheritance) a new SFI.

- e) ***Travel Disclosure:*** All Investigators must disclose reimbursed or sponsored travel undertaken by the Investigator related to Institutional Responsibilities, that is not reimbursed or sponsored by U.S. Federal, state or local governmental agencies, U.S. Institutions of higher education, research institutes affiliated with Institutes of higher education, and Academic teaching hospitals and medical centers within 30 days following reimbursement or within 30 days following the completion of the trip if the organization or entity funds the travel directly. Travel disclosure must include at a minimum:
- (i) the purpose of the trip,
 - (ii) the identity of the organization or entity funding the travel,
 - (iii) the destination, and
 - (iv) the duration of the trip (usually measured in days).

SFI disclosure forms and training requirements are distributed by the Research Compliance Office at the time of hire and annually to Investigators participating in PHS funded research, available on the intranet at <https://inside.icrw.org/tools-resources/phs-funded-research-financial-conflict-interest-policy>, and may be requested from the Research Compliance Office at any time. Regardless of the disclosure requirements, the Investigators are encouraged to disclose any other financial or related interest that could present an actual conflict of interest or be perceived to present a conflict of interest. Upon completion, the form must be returned to the Research Compliance Office for review and processing. Completed forms for employees of the Institution will be maintained by the Human Resources office following review by the Research Compliance office. Completed forms for individuals who are not employees of the Institution that complying via written agreement with this Policy (see section H.1) will be maintained by the Finance Office along with the written agreement.

2. ***Review and Determination:***

Upon receipt of the completed form, if no SFI is disclosed, the form will be forwarded to and maintained in the appropriate personnel file (electronic or hard copy) in the Human Resources Office or contract file in the Finance Office. If the disclosure form reveals a SFI it will be reviewed promptly and prior to the expenditure of any funds by the Institutional Official in consultation with the Senior Research Advisor for determination of whether it constitutes a Financial Conflict of Interest (FCOI). A FCOI will exist when the Institutional Official determines that a SFI could directly and significantly affect the design, conduct, or reporting of PHS funded research (i.e. could be affected by the PHS funded research or is in an entity whose financial interest could be affected by the research). The IO may involve the Investigator in the determination of whether a SFI is related to the PHS funded research or may involve consultants or others deemed appropriate.

If a FCOI exists, the IO will take action to eliminate, reduce, or manage the conflict, as appropriate. If the IO determines that there is a FCOI that can be managed, a written Management Plan is required and must be approved by the IO before the research goes forward or before the Investigator is permitted to participate on such research. The affected Investigator, in consultation with the Institutional Official and Senior Research Advisor, is responsible for developing and submitting a proposed Management Plan.

For ongoing PHS funded research, when an Investigator who is new to participating in the research project discloses a SFI, an existing Investigator discloses a new SFI to the Institution, or the Institution identifies a significant financial interest that was not disclosed timely by an Investigator

or, for whatever reason, was not previously reviewed by the Institution, within 60 days the Institution will:

- a) Review the disclosure and determine whether it is related to PHS funded research
- b) Determine whether a FCOI exists and if so develop a Management Plan that shall specify the actions that have been and will be taken to manage the FCOI.
- c) Depending on the nature of the SFI, determine that additional interim measures are necessary with regard to the Investigator's participation in the PHS funded research project between the date of disclosure and the completion of the Institution's review.

3. *Monitoring and Management of FCOI*

The Institution will take necessary action to monitor and manage any FCOI. Management of an identified FCOI is determined by the IO and requires development and implementation of a Management Plan which will be monitored for compliance on an ongoing basis until the completion of the PHS funded research. If necessary, the IO or Senior Research Advisor will conduct a retrospective review and develop a mitigation report as described below.

Examples of requirements that may be imposed to manage a FCOI include, but are not limited to:

- a) Public disclosure of financial conflicts of interest (e.g., when presenting or publishing the research);
- b) For research projects involving human subjects research, disclosure of financial conflicts of interest directly to participants;
- c) Appointment of an independent monitor capable of taking measures to protect the design, conduct, and reporting of the research against bias resulting from the financial conflict of interest;
- d) Modification of the research plan;
- e) Change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the research;
- f) Reduction or elimination of the financial interest (e.g., sale of an equity interest); or
- g) Severance of relationships that create financial conflicts.

In cases where a FCOI is not identified or managed in a timely manner, because of

- a) Failure by the Investigator to disclose a SFI that is determined by the Institution to constitute a FCOI;
- b) Failure by the Institution to review or manage such a FCOI; or
- c) Failure by the Investigator to comply with a FCOI management plan,

The Institution shall, within 120 days of its determination of noncompliance, complete a retrospective review of the Investigator's activities and the PHS funded research to determine whether the design, conduct, or reporting of the PHS funded research, or any portion thereof, conducted during the period of noncompliance, was biased. Retrospective reviews will be conducted by the Research Compliance Office in consultation with IO.

The retrospective review and detailed findings report will be forwarded to PHS, and include at a minimum the following key elements:

- a) Project number;
- b) Project title;
- c) Principal Investigator or contact Principal Investigator if there are multiple Principal Investigators on the project;
- d) Name of the Investigator with the Financial Conflict of Interest;
- e) Name of the Entity with which the Investigator has a Financial Conflict of Interest;
- f) Reason(s) for the retrospective review;
- g) Detailed methodology used for the retrospective review (e.g., methodology of the review process, composition of the review panel, documents reviewed);
- h) Findings of the review; and
- i) Conclusions of the review.

Based on the results of the retrospective review, the Institution will update the previously submitted FCOI report, if appropriate, specifying the actions that will be taken to manage the FCOI. If bias is found, the Institution shall notify PHS promptly and submit a mitigation report. The mitigation report must include, at a minimum:

- a) The elements documented in the retrospective review above;
- b) A description of the impact of the bias on the research; and
- c) The Institutions plan of action or the actions taken to eliminate or mitigate the effect of the bias (e.g., extent of harm done, including any qualitative and quantitative data to support any actual or future harm; analysis of whether the research is salvageable).

Thereafter, the Institution will submit FCOI reports annually, as specified under the PHS regulations. Depending on the nature of the FCOI, the Institution may determine that additional interim measures are necessary with regard to the Investigator's participation in the PHS funded research between the date that the FCOI or the Investigator's noncompliance is determined and the completion of the Institutions retrospective review.

G. ENFORCEMENT MECHANISMS, REMEDIES, AND NONCOMPLIANCE

1. Enforcement Mechanisms

The Institution shall establish adequate enforcement mechanisms and provide for employee sanctions or other administrative actions to ensure Investigator compliance as appropriate. Possible sanctions might include:

- a) A letter of reprimand sent to the Investigator;
- b) A requirement for special certifications or assurances of compliance;
- c) Restrictions on any grant awards involving the Investigator;
- d) Barring the Investigator from submitting any new proposals for PHS funded research;
- e) Suspension;
- f) Dismissal, or
- g) Other action as appropriate.

2. Remedies

In the event the PHS Awarding Component and/or HHS inquire into any Investigator disclosure of financial interests and the Institution's review (including any retrospective review) of, and response to, such disclosure, regardless of whether the disclosure resulted in the Institution's

determination of a financial conflict of interest the Institution will submit, or permit on site review of, all records pertinent to compliance with this Policy and the 42 CFR 50.

3. *Non-Compliance*

a) Investigator Non-Compliance

If an Investigator fails to comply with this FCOI Policy or a Management Plan and the non-compliance appears to have biased the design, conduct, or reporting of the PHS funded research, the Institution will promptly notify the PHS of the corrective action taken or to be taken.

In the event of an Investigator's failure to comply with this Policy, the Institutional Official may suspend all relevant research activities or pursue other disciplinary action until the matter is resolved or other action deemed appropriate by the Institutional Official is implemented.

The IO's decision to impose sanctions on, or pursue other action via against, an Investigator because of failure to comply with this Policy, or failure to comply with the decision of the Institutional Official, will be described in a written explanation of the decision to the investigator, and, where applicable, other administrative areas of the Institution, and will notify the individual of the right to appeal the decision.

H. **SUBRECIPIENT REQUIREMENTS**

Subrecipient requirements shall be established via a written agreement between the Institution and the subrecipient and where applicable shall address whether subrecipient will follow the FCOI policy of the awardee institution or the FCOI policy of the subrecipient. If the latter, the subrecipient will certify that the subrecipient's FCOI policy complies with the regulation, and will provide any additional information that may be necessary to allow the prime awardee to fulfill their reporting obligations to the PHS. If the subrecipient cannot provide such certification, the written agreement shall state that subrecipient Investigators are subject to the FCOI policy of the awardee Institution for disclosing significant financial interests that are directly related to the subrecipient's work for the awardee Institution.

1. *Subaward issued by ICRW under PHS funded prime awards:*

When the Institution issues a subaward to another organization or individual to carry out a portion of a PHS funded project, the subawardee must comply with the PHS financial conflict of interest regulations. The Institution, therefore, will only grant subawards under PHS funded awards to institutions that have financial conflict of interest policies that comply with the PHS regulations or that will comply via written agreement with the Institutions policy. This requirement will be set forth in the subaward.

- a) If a subawardee Investigator has a FCOI, as determined by the sub-awardees policy, the Institution is responsible for reporting the FCOI to the PHS on behalf of the subawardee. As a result, subawardees must report FCOI to the Institution within 45 days of discovering the FCOI so that the Institution may report it to the PHS in a timely manner. In addition, the Institution is required by PHS to make information regarding subawardee FCOI available to the public. The Institution uses the same method it uses to disclose Institutional FCOI and

notifies the subawardee of any requests for information. Questions regarding the specifics of subawardee FCOI are directed to the subawardee.

- b) Alternatively, if a subawardee Investigator must comply with the Institutions policy and has a FCOI, as determined by the Institution, the Institution will follow the same procedures as outlined in this policy for Institution Investigators.

2. Subawards issued to ICRW under PHS Funded Awards

When the Institution makes a proposal for or receives a subaward from another organization to carry out a portion of a PHS funded project, the Institution must comply with the PHS regulations regarding conflicts of interest. This Policy and these PHS regulations apply to these proposals and awards rather than the policies of the subawarding organization. The Institution provides reports of FCOIs to the subawarding organization for reporting to PHS as specified in the PHS regulations. Reports are provided either in the same form and format as the Institution uses in connection with its direct awards from PHS or via the subawarding organization's form and format. The form and format used will be established via written agreement. The subawarding organization is also responsible for the public accessibility reporting. The subawarding organization may choose to do so either by posting the Institutions report to a publicly available website or responding to written requests within 5 business days.

I. REPORTING REQUIREMENTS

1. Report to PHS and Prime Awardee

In the event reported FCOI or non-compliance requires reporting to PHS, the Institutional Official or designee will report in accordance with PHS regulations. If the funding for the research is made available from a prime PHS awardee, reporting shall be made available to the prime awardee as well so fulfill their reporting obligations to the PHS.

- a) Prior to the expenditure of any funds under a PHS funded research project, the Institution will submit an FCOI Report to PHS regarding any Investigator's SFI found to be conflicting. If the identified FCOI is eliminated prior to the expenditure of PHS-awarded funds, an FCOI Report is **not** required.
- b) For any SFI identified as conflicting subsequent to the Institution's initial FCOI Report during an ongoing PHS funded research project (e.g., upon the participation of an Investigator who is new to the research project), a FCOI report will be provided to PHS within sixty (60) days.
- c) For any FCOI previously reported by the Institution with regard to an ongoing PHS funded research project, the Institution shall provide to PHS an Annual FCOI Report that addresses the status of the FCOI and any changes to the management plan for the duration of the PHS funded research project (including extensions with or without funds). The Annual FCOI report shall specify whether the financial conflict is still being managed or explain why the FCOI no longer exists.

An FCOI Report will include sufficient information to enable PHS to understand the nature and extent of the financial conflict, and to assess the appropriateness of the Institution's management plan. The report shall include, at a minimum:

- a) Project number;

- b) Project Director/Principal Investigator (PD/PI) or Contact PD/PI if a multiple PD/PI model is used;
- c) Name of the Investigator with the Financial Conflict of Interest;
- d) Name of the Entity with which the Investigator has a Financial Conflict of Interest;
- e) Nature of the Financial Interest (e.g., equity, consulting fee, travel reimbursement, honorarium);
- f) 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;
- g) A description of how the Financial Interest relates to the PHS funded research and the basis for the Institution’s determination that the Financial Interest conflicts with such research;
- h) A description of the key elements of the management plan, including: role and principal duties of the conflicted Investigator in the Research project; conditions of the management plan; how the management plan is designed to safeguard objectivity in the research project; confirmation of the Investigator's agreement to the Management Plan; how the management plan will be monitored to ensure Investigator compliance; and
- i) Other information as needed.

J. MAINTENANCE OF RECORDS

1. *Policy:*

The IO shall insure this Policy is maintained, up-to-date, and enforced. In addition, this Policy will be made publically available via the ICRW publicly accessible Web site.

2. *Record Retention:*

The Human Resources Office or Finance Office will maintain all disclosure forms, review and response documentation, and all related records of actions taken by the Institution with respect to disclosures of Financial Interest(s) of Investigators for a period of three (3) years from the date the final expenditures report is submitted to PHS or, where applicable, from other dates specified in 45 CFR 74.53(b) and 92.42 (b) for different situations.

3. *Confidentiality:*

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

K. PUBLIC ACCESSIBILITY REQUIREMENTS

1. *Policy Accessibility:*

This policy shall be posted on the ICRW website: www.ICRW.org.

2. Identified FCOI by Senior/Key Personnel

Reports of FCOI to PHS will be made available to the public upon request. Prior to the Institution's expenditure of any funds under a PHS funded research project, the Institution shall respond to any written requests within five business days of the request, of information concerning any Significant Financial Interest that meets the following criteria:

1. The Significant Financial Interest was disclosed and is still held by the Investigator;
2. A determination has been made that the Significant Financial Interest is related to the PHS funded research; and
3. A determination has been made that the Significant Financial Interest is a Financial Conflict of Interest.

The information that must be made available includes the following, at a minimum:

1. Investigator's name;
2. Investigator's title and role with respect to the research;
3. Name of the entity in which the Significant Financial Interest is held or from which it is received;
4. Nature of the Significant Financial Interest; and
5. Approximate value of the Significant Financial Interest, which value may be expressed as being within a range as described above or if the value of the interest cannot be readily determined through reference to public prices or other reasonable measures of fair market value, a statement confirming that fact.

The Institution will notify the requestor in writing 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 within sixty (60) days of the Institution's identification of a new Financial Conflict of Interest, which would need to be requested subsequently by the requestor. Information concerning the Significant Financial Interests of an Investigator subject to public disclosure shall remain available, for responses to written request for at least three (3) years from the date that the information was most recently updated.