

FINANCIAL CONFLICT OF INTEREST POLICY AND PROCEDURE

INSTITUTED: AUGUST 30, 2017

LAST REVIEWED: MAY 18, 2021

POLICY:

This policy, based upon PHS 42 CFR 50.603-606, promotes objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct, and reporting of research funded under Public Health Service (PHS) grants or cooperative agreements will be free from bias resulting from Investigator financial conflicts of interest.

DEFINITION:

Significant financial interest means:

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:

- 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)
- Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests; or
- The occurrence of any reimbursed or sponsored travel related to the Investigator's institutional responsibilities that is not sponsored or reimbursed by CiPHR, a Federal, state, or local government agency, 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.¹

The term *significant financial interest* does not include the following types of financial interests:

- Salary, royalties, or other remuneration paid by the Center for Innovative Public Health Research (CiPHR) to the Investigator if the Investigator is currently employed or otherwise appointed by CiPHR, including intellectual property rights assigned to CiPHR and agreements to share in royalties related to such rights;
- 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;

¹ NOTE: there is no minimum threshold for the travel disclosure. Any and all supported travel that is not reimbursed or sponsored by the above named institutions must be disclosed. See http://grants.nih.gov/grants/policy/coi/coi_faqs.htm#3190 for more information.

- 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; or
- 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.

CIPHR RESPONSIBILITIES:

- Inform investigators about CiPHR's policy on financial conflicts of interest
- Inform investigators about their disclosure responsibilities for significant financial interests
- Require investigators to complete training prior to engaging in research related to any PHS-funded grant and at least every four years thereafter, and immediately if:
 - CiPHR amends its FCOI policy in a manner that affects Investigator requirements
 - An investigator is new to CiPHR
 - CiPHR finds that an Investigator is not in compliance with the our financial conflict of interest policy or management plan
- Take reasonable steps to ensure that any subrecipient Investigator complies with federal regulations by:
 - Incorporating as part of a written agreement with the subrecipient terms that establish whether the financial conflicts of interest (FCOI) policy of CiPHR or that of the subrecipient will apply to the subrecipient's Investigators.
 - Have the subrecipient certify as part of the agreement that its policy complies with federal policies. If the subrecipient cannot provide such certification, the agreement shall state that subrecipient Investigators are subject to the FCOI policy of CiPHR for disclosing significant financial interests that are directly related to the subrecipient's work for CiPHR.
 - The agreement shall specify time period(s) for the subrecipient to report all identified financial conflicts of interest to their institution, or CiPHR if the subrecipient does not have a federally compliant FCOI policy. Such time period(s) shall be sufficient to enable the subrecipient or CiPHR to provide timely FCOI reports, as necessary, to the PHS as required by federal regulations.
 - Providing FCOI reports to the PHS Awarding Component regarding all financial conflicts of interest of all subrecipient Investigators prior to the expenditure of funds and **within 60 days** of any subsequently identified FCOI.
- Provide initial and ongoing FCOI reports to the PHS as required pursuant to §50.605(b).
- Maintain records relating to all Investigator disclosures of financial interests and CiPHR's review of, and response to, such disclosures (whether or not a disclosure resulted in CiPHR's determination of a financial conflict of interest) and all actions under CiPHR's policy or retrospective review, if applicable, for at least three years from the date the final expenditures report is submitted to the PHS or, where applicable, from other dates specified in 45 CFR 74.53(b) and 92.42 (b) for different situations.
- Have mechanisms to adequately enforce and provide for employee sanctions or other administrative actions to ensure Investigator compliance as appropriate.

INVESTIGATOR RESPONSIBILITIES:

- Disclose significant financial interests. Travel disclosure will include, at a minimum:
 - The purpose of the trip
 - The identity of the sponsor/organizer
 - The destination
 - The duration
 - The Board of Directors will determine if further information is needed, including a determination or disclosure of monetary value, in order to determine whether the travel constitutes any FCOI with the PHS-funded research.
- Complete CiPHR's training program prior to engaging in research related to any PHS-funded grant and at least every four years thereafter, and any time the policy is amended
- Disclose to the Board of Directors the Investigator's significant financial interests (and those of the Investigator's spouse and dependent children) **no later than the time of application** for PHS-funded research.
- Submit an updated disclosure of significant financial interests at least annually during the period of the award. Such disclosure shall include any information that was not disclosed initially to CiPHR or in a subsequent disclosure of significant financial interests (e.g., any financial conflict of interest identified on a PHS-funded project that was transferred from another Institution), and shall include updated information regarding any previously disclosed significant financial interest (e.g., the updated value of a previously disclosed equity interest).
- Submit an updated disclosure of significant financial interests **within thirty days** of discovering or acquiring (e.g., through purchase, marriage, or inheritance) a new significant financial interest.

MANAGEMENT OF FINANCIAL CONFLICTS OF INTEREST

CiPHR's Board of Directors will be the designated officials responsible for reviewing and managing CiPHR Investigator disclosures. As such, they will solicit and review disclosures of significant financial interests from each Investigator who is planning to participate in, or is participating in, PHS-funded research. The Board's responsibilities will be to:

- Determine whether an Investigator's significant financial interest is related to PHS-funded research and, if so related, whether the significant financial interest is a financial conflict of interest. An Investigator's significant financial interest is related to PHS-funded research when CiPHR, through the Board of Directors, reasonably determines that the significant financial interest: could be affected by the PHS-funded research; or is in an entity whose financial interest could be affected by the research. CiPHR may involve the Investigator in the Board of Directors's determination of whether a significant financial interest is related to the PHS-funded research. **A financial conflict of interest exists when CiPHR, through the Board of Directors, reasonably determines that the significant financial interest could directly and significantly affect the design, conduct, or reporting of the PHS-funded research.**
- Take such actions as necessary to manage financial conflicts of interest, including any financial conflicts of a subrecipient Investigator, which requires development and implementation of a management plan and, if necessary, a retrospective review and a mitigation report.

Prior to CiPHR's expenditure of any funds under a PHS-funded research project, the Board of Directors of CiPHR shall review all Investigator disclosures of significant financial interests; determine whether any significant financial interests relate to PHS-funded research; determine whether a financial conflict of interest exists; and, if so, develop and implement a management

plan that shall specify the actions that have been, and shall be, taken to manage such financial conflict of interest.

Examples of conditions or restrictions that might be imposed to manage a financial conflict of interest include, but are not limited to:

- Public disclosure of financial conflicts of interest (e.g., when presenting or publishing the research) including requesting an addendum to previously published research;
- Disclosure of financial conflicts of interest directly to research participants;
- Appointment of an independent monitor capable of taking measures to protect the design, conduct, and reporting of the research against bias resulting from the financial conflict of interest;
- Modification of the research plan;
- Change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the research;
- Reduction or elimination of the financial interest (e.g., sale of an equity interest); or
- Severance of relationships that create financial conflicts.

Whenever, in the course of an ongoing PHS-funded research project, an Investigator who is new to participating in the research project discloses a significant financial interest or an existing Investigator discloses a new significant financial interest to CiPHR, the Board of Directors of CiPHR shall, **within sixty days**: review the disclosure of the significant financial interest; determine whether it is related to PHS-funded research; determine whether a financial conflict of interest exists; and, if so, implement, on at least an interim basis, a management plan that shall specify the actions that have been, and will be, taken to manage such financial conflict of interest. Depending on the nature of the significant financial interest, CiPHR may 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 CiPHR's review.

Whenever CiPHR identifies a significant financial interest that was not disclosed timely by an Investigator or, for whatever reason, was not previously reviewed by CiPHR during an ongoing PHS-funded research project (e.g., was not timely reviewed or reported by a subrecipient), the Board of Directors shall, **within sixty days**: review the significant financial interest; determine whether it is related to PHS-funded research; determine whether a financial conflict of interest exists; and, if so implement, on at least an interim basis, a management plan that shall specify the actions that have been, and will be, taken to manage such financial conflict of interest going forward.

Whenever a financial conflict of interest is not identified or managed in a timely manner including failure by the Investigator to disclose a significant financial interest that is determined by CiPHR to constitute a financial conflict of interest; failure by CiPHR to review or manage such a financial conflict of interest; or failure by the Investigator to comply with a financial conflict of interest management plan, CiPHR shall, within **120 days** of CiPHR's determination of noncompliance, complete a retrospective review of the Investigator's activities and the PHS-funded research project to determine whether any PHS-funded research, or portion thereof, conducted during the time period of the noncompliance, was biased in the design, conduct, or reporting of such research. CiPHR is required to document the retrospective review; such documentation shall include, but not necessarily be limited to, all of the following key elements:

- Project number;
- Project title;
- PD/PI or contact PD/PI if a multiple PD/PI model is used;
- Name of the Investigator with the FCOI;

- Name of the entity with which the Investigator has a financial conflict of interest;
- Reason(s) for the retrospective review;
- Detailed methodology used for the retrospective review (e.g., methodology of the review process, composition of the review panel, documents reviewed);
- Findings of the review; and
- Conclusions of the review.

Based on the results of the retrospective review, if appropriate, CiPHR shall update the previously submitted FCOI report, specifying the actions that will be taken to manage the financial conflict of interest going forward.

If bias is found, CiPHR is required to notify the PHS Awarding Component promptly and submit a mitigation report to the PHS Awarding Component. The mitigation report must include, at a minimum, the key elements documented in the retrospective review above and a description of the impact of the bias on the research project and CiPHR's plan of action or actions taken to eliminate or mitigate the effect of the bias (e.g., impact on the research project; extent of harm done, including any qualitative and quantitative data to support any actual or future harm; analysis of whether the research project is salvageable).

Thereafter, CiPHR will submit FCOI reports annually. Depending on the nature of the financial conflict of interest, CiPHR may determine that additional interim measures are necessary with regard to the Investigator's participation in the PHS-funded research project between the date that the financial conflict of interest or the Investigator's noncompliance is determined and the completion of CiPHR's retrospective review.

Whenever CiPHR implements a management plan related to an identified FCOI, CiPHR shall monitor Investigator compliance with the management plan on an ongoing basis until the completion of the PHS-funded research project.

Prior to CiPHR's expenditure of any funds under a PHS-funded research project, CiPHR shall ensure public accessibility, via CiPHR's publicly accessible website any significant financial interest disclosed to CiPHR that meets the following three criteria:

- The significant financial interest was disclosed and is still held by the senior/key personnel as defined by this subpart;
- CiPHR determines that the significant financial interest is related to the PHS-funded research; and
- CiPHR determines that the significant financial interest is a financial conflict of interest.

The information that CiPHR makes available via the company's publicly accessible website shall include, at a minimum, the following:

- The Investigator's name;
- The Investigator's title and role with respect to the research project;
- The name of the entity in which the significant financial interest is held;
- The nature of the significant financial interest; and
- The approximate dollar value of the significant financial interest (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.

The information that CiPHR posts on our website shall be **updated at least annually**. In addition, CiPHR shall update the website within **sixty days** of CiPHR's receipt or identification of information concerning any additional significant financial interest of the senior/key personnel for the PHS-funded research project that was not previously disclosed, or upon the disclosure of

a significant financial interest of senior/key personnel new to the PHS-funded research project, if CiPHR determines that the significant financial interest is related to the PHS-funded research and is a financial conflict of interest. **The website shall note that the information provided is current as of the date listed and is subject to updates, on at least an annual basis and within 60 days of CiPHR's identification of a new financial conflict of interest.**

Information concerning the significant financial interests of an individual shall remain available on CiPHR's publicly accessible website for at least three years from the date that the information was most recently updated.

REPORTING OF FINANCIAL CONFLICTS OF INTEREST

Prior to CiPHR's expenditure of any funds under a PHS-funded research project, CiPHR shall provide to the PHS Awarding Component an FCOI report regarding any Investigator's significant financial interest found by CiPHR to be conflicting and ensure that CiPHR has implemented a management plan. **In cases in which CiPHR identifies a financial conflict of interest and eliminates it prior to the expenditure of PHS-awarded funds, CiPHR shall not submit an FCOI report to the PHS Awarding Component.**

For any significant financial interest that CiPHR identifies as conflicting subsequent to CiPHR'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), CiPHR shall provide to the PHS Awarding Component, **within sixty days**, an FCOI report regarding the financial conflict of interest and ensure that CiPHR has implemented a management plan. CiPHR also is required to complete a retrospective review to determine whether any PHS-funded research, or portion thereof, conducted prior to the identification and management of the financial conflict of interest was biased in the design, conduct, or reporting of such research. Additionally, if bias is found, CiPHR is required to notify the PHS Awarding Component promptly and submit a mitigation report to the PHS Awarding Component.

Any FCOI report required shall include sufficient information to enable the PHS Awarding Component to understand the nature and extent of the financial conflict, and to assess the appropriateness of CiPHR's management plan. Elements of the FCOI report shall include, but are not necessarily limited to the following:

- Project number;
- PD/PI or Contact PD/PI if a multiple PD/PI model is used;
- Name of the Investigator with the financial conflict of interest;
- Name of the entity with which the Investigator has a financial conflict of interest;
- Nature of the financial interest (e.g., equity, consulting fee, travel reimbursement, honorarium);
- 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;
- A description of how the financial interest relates to the PHS-funded research and the basis for CiPHR's determination that the financial interest conflicts with such research; and
- A description of the key elements of CiPHR's 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
- Other information as needed.

For any financial conflict of interest previously reported by CiPHR with regard to an ongoing PHS-funded research project, CiPHR shall provide to the PHS Awarding Component an annual FCOI report that addresses the status of the financial conflict of interest and any changes to the management plan for the duration of the PHS-funded research project. The annual FCOI report shall specify whether the financial conflict is still being managed or explain why the financial conflict of interest no longer exists. CiPHR shall provide annual FCOI reports to the PHS Awarding Component for the duration of the project period (including extensions with or without funds) in the time and manner specified by the PHS Awarding Component.

FCOI reports for NIH-funded research contracts should be sent to the NIH Office of Acquisition Management and Policy at fcoicontracts@mail.nih.gov as well as through eRA commons: http://era.nih.gov/services_for_applicants/other/fcoi.cfm.

REMEDIES

If the failure of an Investigator to comply with CiPHR's financial conflicts of interest policy or a financial conflict of interest management plan appears to have biased the design, conduct, or reporting of the PHS-funded research, CiPHR shall promptly notify the PHS Awarding Component of the corrective action taken or to be taken. The PHS Awarding Component will consider the situation and, as necessary, take appropriate action, or refer the matter to CiPHR for further action, which may include directions to CiPHR on how to maintain appropriate objectivity in the PHS-funded research project.

Applicability

This policy applies to each Investigator who is planning to participate in, or is participating in, PHS-funded research; of exception are SBIR Program Phase I applications.

Definitions (as provided in § 50.603)

Disclosure of significant financial interests means an Investigator's disclosure of significant financial interests to CiPHR.

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.

FCOI report means CiPHR's report of a financial conflict of interest to a PHS Awarding Component.

Financial interest means anything of monetary value, whether or not the value is readily ascertainable.

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.

Institutional responsibilities means an Investigator's professional responsibilities on behalf of CiPHR, which may include for example activities such as: research, research consultation, teaching, professional practice, institutional committee memberships, and service on panels such as Institutional Review Boards or Data and Safety Monitoring Boards.

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.

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.

PD/PI means a project director or principal Investigator of a PHS-funded research project; the PD/PI is included in the definitions of senior/key personnel and Investigator under this subpart.

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 involved may be delegated, including the National Institutes of Health (NIH).

PHS Awarding Component means the organizational unit of the PHS that funds the research that is subject to this subpart.

Public Health Service Act or PHS Act means the statute codified at 42 U.S.C. 201 *et seq.*

Research means 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). As used in this subpart, 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.

Senior/key personnel means the PD/PI and any other person identified as senior/key personnel by CiPHR in the grant application, progress report, or any other report submitted to the PHS by CiPHR under this subpart.

Small Business Innovation Research (SBIR) Program means the extramural research program for small businesses that is established by the Awarding Components of the Public Health Service and certain other Federal agencies under Public Law 97–219, the Small Business Innovation Development Act, as amended. For purposes of this subpart, the term SBIR Program also includes the Small Business Technology Transfer (STTR) Program, which was established by Public Law 102–564.

Additional resources:

- NIH's Office of Extramural Research Financial Conflict of Interest: <http://grants.nih.gov/grants/policy/coi/>
- FCOI FAQs: http://grants.nih.gov/grants/policy/coi/coi_faqs.htm#3154
- Federal Register posting: <http://www.gpo.gov/fdsys/pkg/FR-2011-08-25/pdf/2011-21633.pdf>
- Web-based tutorial: <http://grants.nih.gov/grants/policy/coi/tutorial2011/fcoi.htm>
- Reporting FCOIs to DHHS: http://era.nih.gov/services_for_applicants/other/fcoi.cfm
- Questions about the Federal policy can be directed to: FCOICompliance@mail.nih.gov

To guide ongoing compliance, we refer to NIH's detailed policy review, dated 2021.04.14

**DETAILED CHECKLIST FOR USE WHEN DEVELOPING OR REVIEWING AN EXISTING POLICY ON
FINANCIAL CONFLICT OF INTEREST (FCOI) per 42 CFR Part 50 Subpart F**

To promote compliance with the FCOI regulation, the FCOI policy should include all the regulatory requirements outlined below and establish a process to ensure compliance with these requirements.

Training Requirements	Regulatory Citation
<input type="checkbox"/> Inform each Investigator of the:	42 CFR 50.604(b)
<input type="checkbox"/> Institution's policy	
<input type="checkbox"/> Investigator's disclosure responsibilities	
<input type="checkbox"/> Federal regulation (See NIH's FAQ L.1. and "FCOI Training" tutorial on NIH's FCOI website)	
<input type="checkbox"/> Require each PHS-supported Investigator to complete FCOI training:	42 CFR 50.604(b)
<input type="checkbox"/> Prior to engaging in research related to any PHS/NIH-funded grant	
<input type="checkbox"/> At least every four (4) years	
<input type="checkbox"/> Immediately, if:	
<input type="checkbox"/> Institution revises its FCOI policy that affects requirements of Investigators	
<input type="checkbox"/> An Investigator is new to an Institution	
<input type="checkbox"/> An Investigator is not in compliance with the policy or management plan	

Disclosure, Review and Monitoring Requirements	Regulatory Citation
<input type="checkbox"/> Require each Investigator to disclose their Significant Financial Interests (SFIs) (see FAQs D.8. and E.26) (and those of the Investigator's spouse and dependent children) related to the Investigator's institutional responsibilities that meet or exceed the regulatory definition of SFI:	42 CFR 50.603 42 CFR 50.604(e)(1)-(3)
<input type="checkbox"/> No later than at the time of application for PHS/NIH-funded research (see FAQ D.35)	
<input type="checkbox"/> At least annually during the period of the award	
<input type="checkbox"/> Within thirty (30) days of discovering or acquiring a new SFI	
<input type="checkbox"/> Designate an Institutional official(s) to:	42 CFR 50.604(d)
<input type="checkbox"/> Solicit and review disclosures of SFIs of the Investigator (and those of the Investigator's spouse and dependent children) related to an Investigator's institutional responsibilities for a determination of FCOI.	
<input type="checkbox"/> Provide adequate guidelines consistent with the regulation for the designated institutional official(s) to determine whether an Investigator's SFI is related to PHS/NIH-funded research and, if so related, whether the SFI is an FCOI.	42 CFR 50.604(f)
NOTE: An SFI is related to PHS/NIH-funded research when the Institution through its designated official(s), reasonably determines that the SFI:	
<ul style="list-style-type: none"> • could be affected by the PHS/NIH-funded research; or • is in an entity whose financial interest could be affected by the research. 	
The Investigator may be involved in making the determination of whether the SFI is related to the PHS/NIH-funded research. An FCOI exists when the Institution, through	

its designated official(s), reasonably determines that the SFI could directly and significantly affect the design, conduct, or reporting of the PHS/NIH-funded research.	
<input type="checkbox"/> Include the examples of conditions or restrictions that might be imposed to manage conflicts of interest (e.g., full public disclosure, appointment of an independent monitor, modification of the research plan, etc. see regulation and NIH's FAQ F.1. for more information on how to manage an FCOI). Adding additional conditions to manage an FCOI is at the institution's discretion.	
<input type="checkbox"/> Require the designated official(s), prior to Institution's expenditure of funds, to:	42 CFR 50.605(a)(1)
<input type="checkbox"/> Review all Investigator SFI disclosures	
<input type="checkbox"/> Determine if any SFIs relate to PHS/NIH-funded research	
<input type="checkbox"/> Determine if an FCOI exists (e.g., the SFI that could directly and significantly affect the design, conduct, or reporting of the NIH-funded research)	
<input type="checkbox"/> Develop and implement a management plan to manage the FCOI(s)	
<input type="checkbox"/> Require when an Investigator who is new to participating in the research project or when an existing Investigator discloses a new SFI, the institution's designated official(s) shall within sixty (60) days review disclosures of SFIs, determine whether the SFI is related to PHS/NIH-funded research; determine whether an FCOI exists; and, if so, implement, on at least an interim basis, a management plan that shall specify the actions that have been, and will be, taken to manage such FCOI.	42 CFR 50.605(a)(2)
<input type="checkbox"/> Require whenever an Institution identifies an SFI that was not disclosed timely by an Investigator or, for whatever reason, was not previously reviewed by the Institution during an ongoing PHS/NIH-funded research project (e.g., was not timely reviewed or reported by a subrecipient), the designated official(s) shall within sixty (60) days review disclosures of SFIs, determine whether the SFI is related to PHS/NIH-funded research; determine whether an FCOI exists; and if so, implement, at least on an interim basis, a management plan that specifies the actions that have been, and will be taken to manage such FCOI going forward.	42 CFR 50.605(a)(3) and (i) – (iii)
<input type="checkbox"/> Take such actions as necessary to manage FCOIs, including any financial conflicts of a subrecipient Investigator, if applicable, and monitor Investigator compliance with management plans until completion of the project.	42 CFR 50.604 (g) 42 CFR 50.605(a)(4)

Reporting Requirements to NIH	Regulatory Citation
<input type="checkbox"/> Send initial, annual (i.e., ongoing) and revised FCOI reports, including all required information defined in the regulation and/or NIH's FAQ H.5 , to the NIH via the eRA Commons FCOI Module for the Institution and its subrecipients, if applicable, as required by the regulation and as stated below:	42 CFR 50.604(h) 42 CFR 50.605(b)
<input type="checkbox"/> Prior to the expenditure of funds	
<input type="checkbox"/> Within sixty (60) days of identification for an Investigator who is newly participating in the project	
<input type="checkbox"/> Within sixty (60) days for new, or newly identified, FCOIs for existing Investigators	
<input type="checkbox"/> At least annually (at the same time as when the Institution is required to submit the annual progress report, multi-year progress report, if applicable, or at time of extension). The annual report will provide the status of the FCOI and any changes to the management plan, if applicable, until the completion of the project.	
<input type="checkbox"/> After a retrospective review to update a previously submitted report, if new information is discovered following completion of the review.	42 CFR 50.605(a)(3)(iii)
<input type="checkbox"/> Notify NIH promptly if bias is found with the design, conduct or reporting of PHS/NIH-funded research and include the requirement to submit a Mitigation Report to explain what	42 CFR 50.605(a)(3)(iii)

action(s) have been or will be taken to mitigate the effects of the bias in accordance with the regulation.	
<input type="checkbox"/> The policy and/or procedures includes all reporting elements (e.g., entity name, name of the investigator with the FCOI, nature of SFI(s), value of the SFI(s), etc.) as required by the regulation.	
<input type="checkbox"/> Notify NIH promptly if an Investigator fails to comply with the Institution's FCOI policy or a FCOI management plan appears to have biased the design, conduct, or reporting of the PHS/NIH-funded research.	42 CFR 50.606(a)
<input type="checkbox"/> Notify NIH promptly and take corrective action for noncompliance with the Institution's policy or the management plan.	

Maintenance of Records**Regulatory Citation**

<input type="checkbox"/> Maintain all FCOI-related records relating to all Investigator disclosures of financial interests and the Institution's review of, and response, to such disclosures (whether or not a disclosure resulted in the Institution's determination of a financial conflict of interest) and all actions under the Institution's policy or retrospective review, if applicable,:	42 CFR 50.604(i)
<input type="checkbox"/> For at least three (3) years from the date the final expenditures report is submitted to the PHS (NIH).	
<input type="checkbox"/> Or, where applicable, from other dates specified in 45 CFR 75.361 for different situations.	

Enforcement Mechanisms and Remedies and Noncompliance**Regulatory Citation**

<input type="checkbox"/> Establish adequate enforcement mechanisms and provide for employee sanctions or other administrative actions to ensure Investigator compliance (e.g., letters of reprimand, restriction on the use of funds, etc.).	42 CFR 50.604(j)
<input type="checkbox"/> Complete a retrospective review (see FAQs in Section I) within 120 days of the Institution's determination of noncompliance when an SFI is not disclosed timely or previously reviewed or whenever an FCOI is not identified or managed in a timely manner, including:	42 CFR 50.605(a)(3)
<input type="checkbox"/> Failure by the Investigator to disclose a significant financial interest that is determined by the Institution to constitute a financial conflict of interest;	
<input type="checkbox"/> Failure by the Institution to review or manage such a financial conflict of interest;	
<input type="checkbox"/> Failure by the Investigator to comply with the financial conflict of interest management plan;	
<input type="checkbox"/> Document the retrospective review which shall include at a minimum the following key elements:	42 CFR 50.605(a)(3)(ii)(B)
<input type="checkbox"/> Project Number	
<input type="checkbox"/> Project Title	
<input type="checkbox"/> PD/PI or contact PD/PI if multiple PD/PI model is used;	
<input type="checkbox"/> Name of the Investigator with the FCOI;	
<input type="checkbox"/> Name of the entity with which the Investigator has an FCOI;	
<input type="checkbox"/> Reasons for the retrospective review;	
<input type="checkbox"/> Detailed methodology used for the retrospective review (e.g., methodology of the review process, composition of the review panel, documentation reviewed);	
<input type="checkbox"/> Findings of the review; and	
<input type="checkbox"/> Conclusions of the review	
<input type="checkbox"/> Ensure that in any case in which the Department of Health and Human Services determines that a PHS/NIH-funded research project of clinical research whose purpose is to	42 CFR 50.606(c)

evaluate the safety or effectiveness of a drug, medical device, or treatment has been designed, conducted, or reported by an Investigator with an FCOI that was not managed or reported by the Institution as required by the regulation, the Institution shall require the Investigator involved to:	
<input type="checkbox"/> Disclose the FCOI in each public presentation of the results of the research, and	
<input type="checkbox"/> To request an addendum to previously published presentations.	

Subrecipient Requirements	Regulatory Citation
<input type="checkbox"/> Address subrecipient requirements (See FAQ K.1).	42 CFR 50.604(c) (also see NIH Grants Policy Statement 15.2.1)
<input type="checkbox"/> Where applicable, establish, via a written agreement, whether the subrecipient will follow the FCOI policy of the awardee Institution or the FCOI policy of the subrecipient.	42 CFR 50.604(c)(1)(i)-(iii)
<input type="checkbox"/> If applicable, obtain a certification from the subrecipient that its FCOI policy complies with the regulation.	
<input type="checkbox"/> If applicable, include in the written subrecipient agreement a requirement for the subrecipient to report identified FCOIs for its Investigators in a time frame that allows the awardee Institution to report identified FCOIs to the NIH as required by the regulation.	
<input type="checkbox"/> Alternatively, if applicable, include in the written agreement a requirement to solicit and review subrecipient Investigator disclosures that enable the awardee Institution to identify, manage and report identified FCOIs to the NIH.	

Public Accessibility Requirements	Regulatory Citation
<input type="checkbox"/> Make the Institution's FCOI policy publicly accessible:	42 CFR 50.604(a) (also see NIH GPS 4.1.10)
<input type="checkbox"/> Post the FCOI policy on the Institution's public Web site	
<input type="checkbox"/> Make available information concerning identified FCOIs held by senior/key personnel (as defined by the regulation, not the NIH Grants Policy Statement), publicly accessible prior to the expenditure of funds. See FAQs in Section G.1 .	42 CFR 50.605(a)(5)(i)-(iv)
The publicly accessible information will:	
<input type="checkbox"/> Include the minimum elements as provided in the regulation	
<input type="checkbox"/> Be posted on a Public Website or made available within five (5) business days of a written request (Determine which option will apply).	
<input type="checkbox"/> Be updated, at least annually (Web site only but any response to a written request should include the updated information)	
<input type="checkbox"/> Be updated, within sixty (60) days of a newly identified FCOI (Web site only but any response to a written request should include the updated information)	
<input type="checkbox"/> Remain available for three (3) years from the date the information was most recently updated.	