

FINACIAL CONFLICT OF INTEREST POLICY AND PROCEDURE

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;
- 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

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 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 foicontracts@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