



**ORIC** OFFICE OF RESEARCH INTEGRITY  
AND COMPLIANCE

# Financial Conflict of Interest Policy

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# Table of Contents

<b>I. Introduction</b> .....	<b>3</b>
<b>II. Scope of This Policy</b> .....	<b>3</b>
<b>III. Definitions</b> .....	<b>4</b>
<b>IV. Responsibilities of the Institution</b> .....	<b>6</b>
<b>V. Responsibilities of Investigators</b> .....	<b>8</b>
<b>VI. Management of Financial Conflicts of Interest</b> .....	<b>8</b>
<b>VII. Reporting of Financial Conflicts of Interest</b> .....	<b>10</b>
<b>VIII. Remedies</b> .....	<b>10</b>

# I. Introduction

The mission of the Pacific Institute for Research and Evaluation is to promote, undertake, and evaluate activities, studies, and programs that improve individual and public health, welfare, and safety. In support of this mission, we create and support an environment within which skilled, innovative, diverse, and dedicated researchers and practitioners work to extend the frontiers of scientific knowledge and its application.

Central to this mission is PIRE's overarching commitment to the ethical conduct of research. For more than four decades, PIRE scientists have been conducting important work on a wide variety of public health and safety issues. PIRE supports the responsibility of each of its researchers by fostering an environment of research ethics and providing institutional oversight.

This Financial Conflict of Interest (FCOI) policy 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, contracts, or cooperative agreements will be free from bias resulting from Investigator FCOI.

It is PIRE's policy that all business and research activities will be conducted in accordance with applicable Federal regulations, Federal policies/guidelines, and contract/grant award terms and conditions. This policy addresses responsibilities, general rules and procedures for identifying and assessing, disclosing, monitoring and reporting, and retaining records regarding FCOI.

A copy of this policy will be posted on PIRE's publicly accessible website (currently <https://www.pire.org/about/legal/>).

# II. Scope of This Policy

This policy serves to address and implement the regulations at 42 CFR 50 Subpart F and 45 CFR 94.

The overall purpose of this policy is to promote objectivity in research and evaluation activities, as well as detect and manage any actual, apparent, or potential bias or conflict of interest, whether financial, personal, or organizational, which may arise during the design, conduct, or reporting of research programs and activities.

In order to maintain this objectivity and compliance with applicable federal regulations, PIRE requires that its potential and existing employees, contractors, sub-recipients, sub-grantees, and consultants (collectively referred to as "Investigator/Individual" or "Individuals") must comply with the requirements of this policy. This policy applies to all PIRE staff and will pertain to all activities funded under any federal contract, grant, cooperative agreement, or sub-recipient agreement, as well as all non-federal grants and contracts with PIRE or its supporting organizations.

### III. Definitions

Contractor: an entity that provides property or services under contract for the direct benefit or use of the Federal Government.

Disclosure of significant financial interest: an Investigator's disclosure of significant financial interest (SFI) to an institution.

Financial conflict of interest (FCOI): an SFI that could directly and significantly affect the design, conduct, or reporting of PHS-funded research.

FCOI report: an Institution's report of an FCOI to a PHS Awarding Component.

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

HHS: the U.S. Department of Health and Human Services and any components of the Department to which the authority involved may be delegated.

Institution: any domestic, foreign, public, or private entity or organization (excluding a Federal agency) that is applying for or receives PHS research funding.

Institutional responsibilities: an Investigator's professional responsibilities on behalf of PIRE including, but not limited to, 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: 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: taking action to address an FCOI, which can include reducing or eliminating the FCOI, to ensure, to the extent possible, that the design, conduct, and reporting of research will be free from bias.

PD/PI: 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: 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: the organizational unit of the PHS that funds the research that is subject to this subpart.

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

Research: a systematic investigation, study, or experiment designed to develop or contribute to generalizable knowledge relating broadly to public health including behavioral and social-sciences research. The term encompasses basic and applied research (e.g., a published article, book, or book chapter) and product development (e.g., a diagnostic test or drug). 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: the PD/PI and any other person identified as senior/key personnel by PIRE in the grant application, progress report, or any other report submitted to the PHS by PIRE under this policy.

Significant financial interest (SFI): 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:

- 1) With regard to any publicly traded entity, an SFI exists if the value of any remuneration received from the entity in the 12 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;
- 2) With regard to any non-publicly traded entity, an SFI exists if the value of any remuneration received from the entity in the 12 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 Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.
- 3) In some cases, 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. a Federal, state, or local government agency,
  - b. an institution of higher education as defined at 20 U.S.C. 1001(a),
  - c. an academic teaching hospital,
  - d. a medical center, or
  - e. a research institute that is affiliated with an institution of higher education.
- 4) The term *significant financial interest* does not include the following types of financial interests:
  - a. salary, royalties, or other remuneration paid by PIRE to the Investigator if the Investigator is currently employed or otherwise appointed by PIRE, including intellectual property rights assigned to PIRE and agreements to share in royalties related to such rights;
  - b. any ownership interest in the Institution held by the Investigator, if the Institution is a commercial or for-profit organization;
  - c. 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;
  - d. 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
  - e. 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.

Small Business Innovation Research (SBIR) Program: 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.

## IV. Responsibilities of the Institution

- 1) PIRE will inform each Investigator of PIRE's policy on FCOI and the Investigator's responsibilities regarding disclosure of SFI.
  - a. PIRE's Human Resources department will provide a copy of the FCOI policy and an acknowledgement form (to be signed and returned within 30 days) to each staff member upon their hiring.
  - b. PIRE requires every staff member to sign a FCOI Acknowledgement Form every year during open enrollment.
  - c. Upon any revision of PIRE's FCOI policy, the revision will be announced, and staff will be required to sign a new acknowledgement form.
- 2) PIRE requires each Investigator to complete FCOI training prior to engaging in research related to any PHS-funding, and then at least every 4 years.
  - a. Investigators new to PIRE must complete FCOI training within 30 days of hiring.
  - b. When PIRE revises its FCOI policy or procedures in any manner that affects the requirements of Investigators, a notice will be sent out to all staff notifying them of the revision and any new or revised requirement for training of Investigators.
  - c. When PIRE finds that an Investigator is not in compliance with PIRE's FCOI policy or management plan, PIRE's Director of Research Integrity and Compliance will prescribe FCOI training in these cases.
  - d. Investigators are required to renew FCOI training prior to the expiration date of their current training (4 years or less).
- 3) If PIRE carries out the PHS-funded research through a subrecipient (e.g., subcontractors or consortium members):
  - a. At the time the application is submitted, all prospective subrecipients are required to complete a Subrecipient Information Form and state whether their own institutional FCOI policy or PIRE's FCOI policy will apply to the project.
  - b. Upon execution of a written Subaward Agreement and before the expenditure of PHS funds, subrecipients will reaffirm whether their own institutional FCOI policy will apply, or they will agree to comply with PIRE's FCOI policy.
  - c. If the subrecipient's Investigators must comply with the subrecipient's FCOI policy, the subrecipient will certify, as part of the Subaward Agreement referenced above, that its policy complies with 42 CFR 50 Subpart F and/or 45 CFR 94. If the subrecipient cannot provide such certification, the agreement will state that subrecipient Investigators are subject to PIRE's FCOI policy for disclosing SFI that is directly related to the subrecipient's work for PIRE.

- d. Additionally, if the subrecipient's Investigators must comply with the subrecipient's FCOI policy, the Subaward Agreement referenced above will specify time period(s) for the subrecipient to report all identified FCOI to PIRE. Such time period(s) will be sufficient to enable PIRE to provide timely FCOI reports, as necessary, to the PHS as required by this subpart.
  - e. Alternatively, if the subrecipient's Investigators must comply with PIRE's FCOI policy, the Subaward Agreement referenced above will specify time period(s) for the subrecipient to submit all Investigator disclosures of SFI to PIRE. Such time period(s) will be sufficient to enable PIRE with its review, management, and reporting obligations, to comply in a timely manner.
- 4) Investigators will submit SFI Disclosure Forms to PIRE's Office of Research Integrity and Compliance (ORIC). The Designated Institutional Officials responsible for reviewing all disclosures will be a team consisting of any two or more of the following: Director of the Office of Research Integrity and Compliance, the Chief Financial Officer, the Chief Executive Officer, the Director of Contracts and Grants, the Director of Human Resources, and an impartial Center Director.
  - 5) PIRE has created guidelines consistent with 42 CFR 50 Subpart F and 45 CFR 94 for determining whether an Investigator's SFI is related to PHS-funded research and, if so related, whether the SFI is an FCOI. An Investigator's SFI is related to PHS-funded research when PIRE, through its Designated Institutional Officials, reasonably determines that the SFI:
    - a. could be affected by the PHS-funded research; or
    - b. is in an entity whose financial interest could be affected by the research. PIRE may involve the Investigator in the Designated Institutional Officials' determination of whether an SFI is related to the PHS-funded research. A FCOI exists when PIRE, through its Designated Institutional Officials, reasonably determines that the SFI could directly and significantly affect the design, conduct, or reporting of the PHS-funded research.
  - 6) PIRE's Director of Research Integrity and Compliance will file initial and ongoing FCOI reports to the appropriate PHS funding agency.
  - 7) PIRE will maintain records relating to all Investigator disclosures of financial interests and PIRE's review of, and response to, such disclosures (whether or not a disclosure resulted in PIRE's determination of an FCOI) and all actions under PIRE's policy or retrospective review, if applicable, for at least 3 years from the date the final expenditures report is submitted to the PHS or, where applicable, from other dates specified in 45 CFR 75.361 for different situations. These records will be maintained by the Office of Research Integrity Compliance.
  - 8) PIRE has established enforcement mechanisms and provided for employee sanctions or other administrative actions to ensure Investigator compliance as appropriate, including mandated public disclosure, loss of investigator privileges, and other actions up to and including termination of employment.
  - 9) PIRE will certify, in each application for funding to which this policy applies, that PIRE:
    - a. has in effect an up-to-date, written, and enforced administrative process to identify and manage FCOI with respect to all research projects for which funding is sought or received from the PHS;
    - b. will promote and enforce Investigator compliance with this subpart's requirements including those pertaining to disclosure of SFI;
    - c. will manage FCOI and provide initial and ongoing FCOI reports to the PHS Awarding Component;

- d. agrees to make information available promptly upon request to the HHS relating to any Investigator disclosure of financial interests and PIRE's review of, and response to, such disclosure, whether or not the disclosure resulted in PIRE's determination of an FCOI; and
- e. will fully comply with the requirements of the conflict of interest policies at 42 CFR 50 Subpart F and 45 CFR 94.

## V. Responsibilities of Investigators

- 1) Each Investigator is required to complete training regarding FCOI prior to engaging in research related to any PHS-funded grant and at least every 4 years, and immediately when any of the following circumstances apply:
  - a. When we revise our FCOI policy or procedures,
  - b. An Investigator is new to PIRE, or
  - c. PIRE finds that an Investigator is not in compliance with PIRE's FCOI policy or management plan.
- 2) Disclosure of SFI:
  - a. Each Investigator who is planning to participate in PHS-funded research must disclose to PIRE's Designated Institutional Officials (via the Director of Research Integrity and Compliance) the Investigator's SFI (and those of the Investigator's spouse and dependent children) no later than the time of application for PHS-funded research.
  - b. Each Investigator who is participating in the PHS-funded research must submit an updated disclosure of SFI at least annually, in accordance with the specific time period prescribed by PIRE, during the period of the award.
  - c. Each Investigator who is participating in the PHS-funded research must submit an updated disclosure of SFI within 30 days of discovering or acquiring (e.g., through purchase, marriage, or inheritance) a new SFI.
  - d. When an Investigator is required to disclose the occurrence of any reimbursed or sponsored travel (see definition of SFI), the disclosure must include, at a minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration. The Designated Institutional Officials 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.

## VI. Management of Financial Conflicts of Interest

- 1) Prior to PIRE's expenditure of any funds under a PHS-funded research project, PIRE's Designated Institutional Officials will review all Investigator disclosures of SFI to determine:
  - a. whether any SFI relates to PHS-funded research,
  - b. whether an FCOI exists and, if it does, develop and implement a management plan that specifies the actions that have been, and will be, taken to manage the FCOI.

- 2) Within 60 days (in the course of an ongoing PHS-funded research project) of a new (to the project) Investigator disclosing an SFI or an existing Investigator disclosing a new SFI to PIRE, the Designated Institutional Officials will, within 60 days:
  - a. review the disclosure of the SFI;
  - b. determine whether it is related to PHS-funded research;
  - c. determine whether an FCOI exists; and, if so, implement, on at least an interim basis, a management plan that specifies the actions that have been, and will be, taken to manage such FCOI.
- 3) Within 60 days of PIRE's identification of an SFI that was not disclosed in a timely manner by an Investigator or, for whatever reason, was not previously reviewed by PIRE during an ongoing PHS-funded research project (e.g., was not timely reviewed or reported by a subrecipient), the Designated Institutional Officials will, within 60 days:
  - a. review the SFI;
  - b. determine whether it is related to PHS-funded research;
  - c. determine whether an FCOI exists; and, if so, implement, on at least an interim basis, a management plan that will specify the actions that have been, and will be, taken to manage such FCOI going forward.
  - d. In addition, whenever an FCOI is not identified or managed in a timely manner (including failure by the Investigator to disclose an SFI that is determined by PIRE to constitute an FCOI; failure by PIRE to review or manage such an FCOI; or failure by the Investigator to comply with an FCOI management plan), PIRE will:
    - i. within 120 days of its determination of noncompliance, complete and document 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;
    - ii. If appropriate, based on the results of the retrospective review, update the previously submitted FCOI report, specifying the actions that will be taken to manage the FCOI going forward.
    - iii. If bias is found, notify the PHS Awarding Component promptly and submit a mitigation report to the PHS Awarding Component. Depending on the nature of the FCOI, PIRE 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 FCOI or the Investigator's noncompliance is determined and the completion of PIRE's retrospective review.
- 4) Whenever PIRE implements a management plan, it will monitor Investigator compliance with the management plan on an ongoing basis until the completion of the PHS-funded research project.
- 5) PIRE will ensure public accessibility, via written response, to any requestor within 5 business days of a request of information concerning any SFI disclosed to PIRE that meets the following three criteria: The SFI was disclosed and is still held by the Investigator; PIRE determines that the SFI is related to the PHS-funded research; and PIRE determines that the SFI is an FCOI.

The written response to any requestor within 5 business days of a request, will include, at a minimum, the following:

- a. the Investigator's name;
- b. the Investigator's title and role with respect to the research project;
- c. the name of the entity in which the SFI is held;
- d. the nature of the SFI;

- e. the approximate dollar value of the SFI (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; and
- f. If PIRE responds to written requests under this subsection, it will note in its written response that the information provided is current as of the date of the correspondence and is subject to updates, on at least an annual basis and within 60 days of PIRE's identification of a new FCOI, which should be requested subsequently by the requestor.

Information concerning the SFI of an individual subject to this section will remain available, for responses to written requests or for posting via PIRE's publicly accessible web site for at least 3 years from the date that the information was most recently updated.

- 6) In addition to the types of FCOI that must be managed pursuant to this section, PIRE may require the management of other FCOI in its policy on FCOI, as PIRE deems appropriate.

## VII. Reporting of Financial Conflicts of Interest

- 1) Prior to PIRE's expenditure of any funds under a PHS-funded research project, PIRE will provide to the PHS Awarding Component an FCOI report regarding any Investigator's SFI found by PIRE to be conflicting and ensure that PIRE has implemented a management plan. In cases in which PIRE identifies an FCOI and eliminates it prior to the expenditure of PHS-awarded funds, PIRE need not submit an FCOI report to the PHS Awarding Component.
- 2) For any SFI that PIRE identifies as conflicting subsequent to its 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), PIRE will provide to the PHS Awarding Component, within 60 days, an updated FCOI report regarding the FCOI.
- 3) For any FCOI previously reported, PIRE will provide to the PHS Awarding Component 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. The annual FCOI report will specify whether the FCOI is still being managed or explain why the FCOI no longer exists. PIRE will 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.

## VIII. Remedies

- 1) If the failure of an Investigator to comply with PIRE's FCOI policy or an FCOI management plan appears to have biased the design, conduct, or reporting of the PHS-funded research, PIRE will promptly notify the PHS Awarding Component of the corrective action taken or to be taken.
- 2) The PHS Awarding Component and/or HHS may inquire at any time before, during, or after award into any Investigator disclosure of financial interests and PIRE's review (including any

retrospective review) of, and response to, such disclosure, regardless of whether the disclosure resulted in PIRE's determination of an FCOI. PIRE is required to submit, or permit on-site review of, all records pertinent to compliance with 42 CFR 50 Subpart F and 45 CFR 94. To the extent permitted by law, HHS will maintain the confidentiality of all records of financial interests. On the basis of its review of records or other information that may be available, the PHS Awarding Component may decide that a particular FCOI will bias the objectivity of the PHS-funded research to such an extent that further corrective action is needed or that PIRE has not managed the FCOI in accordance with 42 CFR 50 Subpart F and 45 CFR 94. The PHS Awarding Component may determine that imposition of specific award conditions under 45 CFR 75.207, or suspension of funding or other enforcement action under 45 CFR 75.371, is necessary until the matter is resolved.

- 3) In any case in which the HHS determines that a PHS-funded project of clinical research whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment has been designed, conducted, or reported by an Investigator with an FCOI was not managed or reported by PIRE as required by this subpart, PIRE will require the Investigator involved to disclose the FCOI in each public presentation of the results of the research and to request an addendum to previously published presentations.