

**Definitions (based on 42 CFR Part 50, Subpart F, §50.603).**

1. 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.
2. 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).
3. PHS Awarding Component means the organizational unit of the PHS that funds the research that is subject to this policy.
4. Public Health Service Act or PHS Act means the statute codified at 42 U.S.C. 201 et seq.
5. Institution means any domestic or foreign, public or private, entity or organization (excluding a Federal agency) that is applying for, or that receives, PHS research funding.
6. Institutional responsibilities means an Investigator's professional responsibilities on behalf of the Institution, and as defined by the Institution in its policy on financial conflicts of interest, 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.
7. 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.
8. 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.
9. 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.
10. Senior/key personnel means the PD/PI and any other person identified as senior/key personnel by the Institution in the grant application, progress report, or any other report submitted to the PHS by the Institution under this subpart.
11. Financial interest means anything of monetary value, whether or not the value is readily ascertainable.
12. Significant financial interest (SFI) means:

(1) A financial interest consisting of one or more of the following interests of the Investigator (and those of the Investigator's spouse and dependent children) that reasonably appears to be related to the Investigator's institutional responsibilities:

1. With regard to any publicly traded entity, a significant financial interest exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure and the value of any equity interest in the entity as of the date of disclosure, when aggregated, exceeds \$5,000. For purposes of this definition, remuneration includes salary and any payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorship); equity interest includes any stock, stock option, or other ownership interest, as determined through reference to public prices or other reasonable measures of fair market value;
  1. With regard to any non-publicly traded entity, a significant financial interest exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure, when aggregated, exceeds \$5,000, or when the Investigator (or the Investigator's spouse or dependent children) holds any equity interest (e.g., stock, stock option, or other ownership interest); or
  2. Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.

(2) Investigators also must disclose the occurrence of any reimbursed or sponsored travel (i.e., that which is paid on behalf of the Investigator and not reimbursed to the Investigator so that the exact monetary value may not be readily available), related to their institutional responsibilities; provided, however, that this disclosure requirement does not apply to travel that is reimbursed or sponsored by a Federal, state, or local government agency, an Institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education. The Institution's FCOI policy will specify the details of this disclosure, which will include, at a minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration. In accordance with the Institution's FCOI policy, the institutional official(s) will determine if further information is needed, including a determination or disclosure of monetary value, in order to determine whether the travel constitutes an FCOI with the PHS-funded research.

(3) The term significant financial interest does not include the following types of financial interests: salary, royalties, or other remuneration paid by the Institution to the Investigator if the Investigator is currently employed or otherwise appointed by the Institution, including intellectual property rights assigned to the Institution and agreements to share in royalties related to such rights; any ownership interest in the Institution held by the Investigator, if the Institution is a commercial or for-profit organization; 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 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.

1. Disclosure of significant financial interests (SFI Disclosure) means an Investigator's disclosure of significant financial interests to an Institution.
2. FCOI report means an Institution's report of a financial conflict of interest to a PHS Awarding Component.
3. "FCOI Management" 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.

4. 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.
5. An FCOI exists when PeDRA, through its designated FCOI Management Official (FCOIMO), reasonably determines that: (i) a significant financial interest could directly and significantly affect the design, conduct or reporting of the PHS-funded research, or (ii) the significant financial interest could be affected by the PHS-funded research; or (iii) the significant financial interest is in an entity whose financial interest could be affected by the research. PeDRA may involve the Investigator in the FCOIMO's determination of whether a significant financial interest is related to the PHS-funded research.
6. 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.
7. An "*SFI Disclosure*" is a report that each Investigator shall submit: (a) annually to the FCOIMO; (b) in the event of certain sponsored travel, as set forth in the definition of "significant financial interest," above; and (c) within thirty (30) days of an Investigator discovering or acquiring any significant financial interest.
8. "*Training Requirement*" means training related to FCOI and required by law. All PeDRA Investigators are required to complete the Training Requirement. The training must be updated no less frequently than every four years or as specified in the grant or contract. Information and other resources developed by NIH are available on the NIH Web site: (<https://grants.nih.gov/grants/policy/coi/index.htm>).

## **Purpose**

The purpose of this policy is to comply with applicable law and to ensure the objectivity of the research conducted by PeDRA, its employees, contractors, and consultants by establishing standards regarding the design, conduct and reporting of PHS-funded research to ensure that it is free from bias resulting from FCOI. Investigators applying for and working on PHS-funded research projects must disclose SFIs that are related to the Investigator's institutional responsibilities. This policy provides the framework to identify, evaluate and correct or remove real, apparent and potential conflicts of interest.

This policy requires that each investigator, subrecipient, subgrantee, collaborator and consultant affiliated with PeDRA on a PHS-funded project be in compliance with 42 CFR Part 50, Subpart F for grants and cooperative agreements (and 45 CFR Part 94 for contracts). This legislation states NIH's commitment to ensure that the NIH-supported research is conducted without bias and with the highest scientific and ethical standards.

PeDRA intends to use this same FCOI standard for all other Federal agency grants and contracts, as tailored or amended accordingly.

## **Investigators' Reporting and SFI Disclosures**

Each Investigator shall submit disclosures of SFIs (using the Company SFI Disclosure Form) to FCOIMO as follows:

(a) an updated annual SFI Disclosure;

(b) within thirty (30) days of an Investigator discovering or acquiring (e.g., through purchase, marriage, or inheritance) any SFI; and

(c) in the event of certain sponsored travel, as set forth in the definition of “significant financial interest,” above.

The FCOIMO will review each SFI Disclosure and evaluate whether any such SFI Disclosure has given rise to an FCOI. If no FCOI is found, the SFI Disclosure will be filed with the FCOIMO’s SFI Disclosure records. If a FCOI is identified it will be put on the FCOI report through the eRA Commons FCOI module (or, where the Company is a subgrantee or subawardee, then the Company will report the FCOI as required under the applicable subgrant or subaward agreement) prior to expending any PHS funds. The Company will then report any new FCOIs to the Awarding Component within 60 days. If an Investigator with an FCOI conducts a PHS-funded Research, the Company shall disclose the FCOI in each public presentation related to the results of the PHS-funded Research.

### **Exclusions**

PHS regulations exclude applications for Phase I support under the Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) programs from FCOI disclosure requirements.

### **Training and Compliance (based on 42CFR Part F, §50.604)**

#### **PeDRA shall:**

1. inform each Investigator of its policy on FCOI, the Investigator’s responsibilities regarding disclosure of SFIs, and of these regulations, and require each Investigator to complete training regarding the same prior to engaging in research related to any PHS-funded grant and at least every four years, and immediately when any of the following circumstances apply:
  1. PeDRA revises its FCOI policies or procedures in any manner that affects the requirements of Investigators;
  2. An Investigator is new to an Institution; or
  3. PeDRA finds that an Investigator is not in compliance with the Institution’s FCOI policy or management plan.
2. require that each Investigator who is planning to participate in the PHS-funded research disclose to PeDRA’s FCOIMO the Investigator’s SFIs (and those of the Investigator’s spouse and dependent children) no later than the time of application for PHS-funded research.
3. take such actions as necessary to manage FCOIs, including any financial conflicts of a subrecipient Investigator pursuant to paragraph (c) of this section. Management of an identified FCOI requires development and implementation of a management plan and, if necessary, a retrospective review and a mitigation report pursuant to §50.605(a).
4. provide initial and ongoing FCOI reports to the PHS as required pursuant to §50.605(b).

If PeDRA carries out the PHS-funded research through a subrecipient (e.g., subcontractors or consortium members), PeDRA shall take reasonable steps to ensure that any subrecipient Investigator complies with this policy by:

(1) Incorporating as part of a written agreement with the subrecipient terms that establish whether the FCOI policy of the awardee Institution or that of the subrecipient will apply to the subrecipient’s Investigators.

(i) If the subrecipient's Investigators must comply with the subrecipient's FCOI policy, the subrecipient shall certify as part of the agreement referenced above that its policy complies with this subpart. If the subrecipient cannot provide such certification, the agreement shall state that subrecipient Investigators are subject to the FCOI policy of the awardee Institution for disclosing SFIs that are directly related to the subrecipient's work for the awardee Institution;

(ii) Additionally, if the subrecipient's Investigators must comply with the subrecipient's FCOI policy, the agreement referenced above shall specify time period(s) for the subrecipient to report all identified FCOIs to the awardee Institution. Such time period(s) shall be sufficient to enable the awardee Institution to provide timely FCOI reports, as necessary, to the PHS as required by this subpart;

(iii) Alternatively, if the subrecipient's Investigators must comply with the awardee Institution's FCOI policy, the agreement referenced above shall specify time period(s) for the subrecipient to submit all Investigator disclosures of SFIs to the awardee Institution. Such time period(s) shall be sufficient to enable the awardee Institution to comply timely with its review, management, and reporting obligations under this subpart.

(2) Providing FCOI reports to the PHS Awarding Component regarding all FCOI of all subrecipient Investigators consistent with this subpart, i.e., prior to the expenditure of funds and within 60 days of any subsequently identified FCOI.

### **Records Management**

PeDRA shall maintain 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 an FCOI) and all actions under the Institution'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 75.361 for different situations.

### **Enforcement**

#### **PeDRA shall:**

1. establish adequate enforcement mechanisms and provide for employee sanctions or other administrative actions to ensure Investigator compliance as appropriate;
2. certify, in each application for funding to which this policy applies, that PeDRA:
  1. Has in effect an up-to-date, written, and enforced administrative process to identify and manage FCOIs with respect to all research projects for which funding is sought or received from the PHS;
  2. Shall promote and enforce Investigator compliance with this subpart's requirements including those pertaining to disclosure of SFIs;
  3. Shall manage FCOIs and provide initial and ongoing FCOI reports to the PHS Awarding Component consistent with this subpart;
  4. Agrees to make information available, promptly upon request, to the HHS relating to any Investigator disclosure of financial interests and the Institution's review of, and response to, such disclosure, whether or not the disclosure resulted in the Institution's determination of an FCOI; and
  5. Shall fully comply with the requirements of 42CFR Part F, §50.604.

### **Remedies and Penalties for Non-Performance (based on 42CFR, Part F, §50.606)**

(a) If the failure of an Investigator to comply with PeDRA's FCOI policy or an FCOI management plan appears to have biased the design, conduct, or reporting of the PHS-funded research, PeDRA shall promptly notify the PHS Awarding Component of the corrective action taken or to be taken.

(b) PeDRA shall submit, or permit onsite review of, all records pertinent to compliance with this subpart.

(c) 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 that was not managed or reported by PeDRA as required by this policy,

(d) PeDRA shall 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.

### **Management and reporting of financial conflicts of interest (based on 42CFR, Part F, §50.605)**

(1) Prior to PeDRA's expenditure of any funds under a PHS-funded research project, PeDRA's FCOIMO will review all Investigator disclosures of SFIs; determine whether any SFIs relate to PHS-funded research; determine whether an FCOI 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 FCOI. Examples of conditions or restrictions that might be imposed to manage an FCOI include, but are not limited to:

(i) Public disclosure of FCOIs (e.g., when presenting or publishing the research);

(ii) For research projects involving human subjects research, disclosure of FCOIs directly to participants;

(iii) Appointment of an independent monitor capable of taking measures to protect the design, conduct, and reporting of the research against bias resulting from the FCOI;

(iv) Modification of the research plan;

(v) Change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the research;

(vi) Reduction or elimination of the financial interest (e.g., sale of an equity interest); or

(vii) Severance of relationships that create financial conflicts.

(2) Whenever, in the course of an ongoing PHS-funded research project, an Investigator who is new to participating in the research project discloses a SFI or an existing Investigator discloses a new SFI to PeDRA, its designated FCOIMO official(s) shall, within sixty (60) days: review the disclosure of the SFI; determine whether it is related to PHS-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. Depending on the nature of the SFI, PeDRA 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 the Institution's review.

(3) Whenever PeDRA identifies a SFI that was not disclosed in a timely fashion by an Investigator or, for whatever reason, was not previously reviewed by PeDRA during an ongoing PHS-funded research project (e.g., was not reviewed or reported by a subrecipient in a timely fashion), the designated official(s) shall, within sixty (60) days: review the SFI; determine whether it is related to PHS-funded research; determine whether an FCOI exists; and, if so:

(i) 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 going forward;

(ii) (a) In addition, whenever an FCOI is not identified or managed in a timely manner including failure by the Investigator to disclose a SFI that is determined by the Institution to constitute an FCOI; failure by the Institution to review or manage such an FCOI; or failure by the Investigator to comply with an FCOI management plan, PeDRA shall, within 120 days of the PeDRA'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.

(b) PeDRA shall document the retrospective review; such documentation shall include, but not necessarily be limited to, all of the following key elements:

(1) Project number;

(2) Project title;

(3) PD/PI or contact PD/PI if a multiple PD/PI model is used;

(4) Name of the Investigator with the FCOI;

(5) Name of the entity with which the Investigator has an FCOI;

(6) Reason(s) for the retrospective review;

(7) Detailed methodology used for the retrospective review (e.g., methodology of the review process, composition of the review panel, documents reviewed);

(8) Findings of the review; and

(9) Conclusions of the review.

(iii) Based on the results of the retrospective review, if appropriate, the Institution shall update the previously submitted FCOI report, specifying the actions that will be taken to manage the FCOI going forward. If bias is found, the Institution 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 the Institution'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, the Institution will submit FCOI reports annually, as specified elsewhere in this subpart. Depending on the nature of the FCOI, an Institution 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 PeDRA's retrospective review.

(4) Whenever PeDRA implements an FCOI management plan, PeDRA shall monitor Investigator compliance with the management plan on an ongoing basis until the completion of the PHS-funded research project.

(5)(i) Prior to PeDRA's expenditure of any funds under a PHS-funded research project, PeDRA shall ensure public accessibility, via a written response to any requestor within five (5) business days of a request, of information concerning any SFI disclosed to PeDRA that meets the following three criteria:

(A) The SFI was disclosed and is still held by the senior/key personnel as defined by this subpart;

(B) PeDRA determines that the SFI is related to the PHS-funded research; and

(C) PeDRA determines that the SFI is an FCOI.

(ii) The information that PeDRA makes available via a publicly accessible website or written response to any requestor within five (5) business days of a request, 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 SFI is held; the nature of the SFI; and 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.

(iii) FCOI-related information on PeDRA's publicly accessible Web site shall be updated at least annually. In addition, PeDRA shall update the Web site within sixty (60) days of PeDRA's receipt or identification of information concerning any additional SFI of the senior/key personnel for the PHS-funded research project that was not previously disclosed, or upon the disclosure of a SFI of senior/key personnel new to the PHS-funded research project, if the Institution determines that the SFI is related to the PHS-funded research and is an FCOI. The Web site 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 sixty (60) days of the Institution's identification of a new FCOI. If PeDRA responds to written requests for the purposes of this subsection, PeDRA 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 sixty (60) days of PeDRA's identification of a new FCOI, which should be requested subsequently by the requestor.

(iv) Information concerning the SFIs of an individual subject to paragraph (a)(5) of this section shall remain available, for responses to written requests for at least three years from the date that the information was most recently updated.

**Point of Contact:** If you have questions or concerns regarding FCOI (or potential FCOI), please contact Michael Siegel, PeDRA's FCOIMO, by email at [mike.siegel@pedraresearch.org](mailto:mike.siegel@pedraresearch.org)

## Financial Conflict of Interest Disclosure Form

Persons completing this form are expected to have read and understood the PeDRA's Financial Conflict of Interest (FCOI) Policy on Federal Grants and Contracts. If you have any questions regarding that policy, please contact Michael Siegel, PeDRA's FCOIMO, at [mike.siegel@pedraresearch.org](mailto:mike.siegel@pedraresearch.org).

### Disclosure Type:

- Initial
- Annual
- Project specific

1. Do you, your spouse, or dependent children have a "significant financial interest (SFI)" (as defined on the PeDRA's FCOI Policy) that would reasonably appear to be affected by your PHS-funded research?

- Yes
- No

If yes, please describe on a separate page the nature and extent of your/their affiliation.

2. Do you, your spouse or dependent children have an SFI in any business or legal entity whose financial interests would reasonably appear to be affected by PHS-funded research?

- Yes
- No

If yes, please describe on a separate page the nature and extent of your/their affiliation.

### I certify that:

*I have read PeDRA's Policy on Financial Conflict of Interest on Federal Grants and Contracts, and I have made all required financial disclosures. (If the program leader, principal investigator or project director) I have made every effort to ensure that all Investigators (see policy for definition) responsible for the design, conduct or reporting of the research have submitted required disclosures.*

Signature \_\_\_\_\_

Date: \_\_\_\_\_

Printed name: \_\_\_\_\_

Project Title:

Project Sponsor:

Comments (if any):