

<b>DEPARTMENT:</b> Clinical Operations Group	<b>POLICY DESCRIPTION:</b> Investigator Conflicts of Interest in PHS Grants
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<b>APPROVED BY:</b> Ethics and Compliance Policy Committee	

**SCOPE:** This policy relates to the Institution's (defined as all HCA-affiliated hospitals, ambulatory surgery centers, physician practices, and all other HCA-affiliated facilities) obligations to assure the review of significant financial interests held by its Investigators (which extends to their spouse and dependent children) of federally-funded clinical research to determine if there is a financial conflict of interest with any particular federally-funded clinical research project and, if so, to appropriately manage it. This policy does not pertain to non-federally funded research or to research projects, which the Institution is a subrecipient and agrees to abide by the prime recipient's related policies instead of managing this process on its own.

**PURPOSE:** The Institution shall identify and manage any Investigator's Financial Conflicts of Interests related to Public Health Service (PHS) funded research in accordance with PHS regulations.

**DEFINITIONS:**

**These definitions are rooted in 2CFR200 and 42CFR50 and are applicable to this policy.**

**Awardee Institution** means any domestic or foreign, public or private, entity or organization (excluding a Federal agency) that is applying for, or that receives funding directly from, PHS.

**FCOI Report** means an Institution's report of a Financial Conflict of Interest to a PHS Awarding Component.

**Financial Conflict of Interest** or FCOI means a Significant Financial Interest that could directly and significantly affect the design, conduct, or reporting of PHS-funded research.

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

**Federal Wide Assurance (FWA)** means a formal written, binding commitment that is submitted to the Office for Human Research Protections (OHRP) in which an institution promises to comply with the U.S. Department of Health and Human Services (DHHS) regulations governing the protection of human subjects in research. An FWA is only required for an institution that is engaged in the review and approval process for DHHS conducted or supported (i.e., federally- funded) human research.

**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.

**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 PHS, or proposed for such funding, which may include, for example, collaborators or consultants.

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**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.

**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 policy, 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 the Institution in the grant application, progress report, or any other report submitted to PHS by the Institution.

**Significant Financial Interest** or SFI means:

- 1) A financial interest consisting of at least one of the following scenarios applicable to the Investigator or to his/her spouse and/or dependent children that appears to be related to the Investigator's institutional responsibilities:
  - (i) If a salary from a publicly-traded entity and any payments for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorship) received in the last twelve months in addition to the value of any equity interests (any stock, stock option, or other ownership interest, as determined through reference to public prices or other reasonable measures of fair market value) in the entity, as of the date of disclosure, exceeds \$5,000.
  - (ii) If a salary from a non-publicly traded entity and any payments for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorship) received in the twelve months preceding the disclosure exceeds \$5,000, or when the Investigator (or the Investigator's spouse or dependent children) holds any equity interest (any stock, stock option, or other ownership interest).
  - (iii) If Intellectual property rights and interests (e.g., patents, copyrights) are to be rewarded upon receipt of income related to such rights and interests.

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- 2) 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 within the last twelve months; provided, however, that this 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.
- 3) The term significant financial interest does not include the following types of financial interests:
  - (i) 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.
  - (ii) Any ownership interest in the Institution held by the Investigator, if the Institution is a commercial or for-profit organization.
  - (iii) 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.
  - (iv) 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.

**Subrecipient** means the entity (or Institution if that may be the case) that is receiving funds from the awardee institution (or another subrecipient) to do research on behalf of PHS.

**POLICY:**

**SECTION I: Responsibilities of the Institution**

1. The Institution will refer to this policy as its policy on financial conflicts of interest for PHS funded studies and HCA shall make it available via its publicly accessible Website.
2. The Institution will provide training to Investigators about this policy and their responsibilities regarding disclosure of SFIs. Such training will be provided to Investigators prior to their engaging in research related to any PHS-funded grant, at least

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<p>every four years thereafter, and immediately when any of the following circumstances apply:</p> <ul style="list-style-type: none"> <li>(a) The Institution revises this policy in any manner that affects the requirements of Investigators;</li> <li>(b) The Investigator is new to an Institution;</li> <li>(c) The Institution finds that the Investigator is not in compliance with this policy or an FCOI management plan; or</li> <li>(d) If the Investigator discovers or acquires (e.g., through purchase, marriage, or inheritance) a new Significant Financial Interest.</li> </ul> <p>3. The Institutional Official shall solicit and review disclosures of Significant Financial Interests from each Investigator who is planning to participate in, or is participating in, the PHS-funded research. The Institutional Official is the same person named on the awardee Institution's Federal Wide Assurance.</p> <p>4. At the discretion of the Institutional Official, he or she may delegate one or more designated officials, who are qualified, to review the information necessary to determine whether an FCOI exists. Examples of qualifications include: if he or she has sufficient knowledge of the subject matter that is included in the PHS- funded research</p> <p>5. Investigators who are participating in the PHS-funded research are required to submit an updated disclosure of SFIs at least annually, in accordance with the specific time period prescribed by the Institution, during the period of the award. Such disclosure shall include any information that was not disclosed initially to the Institution and shall include updated information regarding any previously disclosed Significant Financial Interest.</p> <p>6. An Investigator's Significant Financial Interest is related to PHS-funded research when the Institution, through its Institutional Official(s) or designee, reasonably determines that the Significant Financial Interest could (i) be affected by the PHS-funded research; or (ii) is in an entity whose financial interest could be affected by the research. For example, if the Investigator's spouse owns stock in a certain company whose products are being researched or tested in this particular study.</p> <p>7. The Investigator will need to disclose to the Institution's designated official(s) his or her Significant Financial Interests (and those of his or her spouse and dependent children) no later than the time of application for PHS-funded research.</p> <p>8. The Institution may involve the Investigator in the designated official's's determination of whether an SFI is related to the PHS-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-funded research.</p>
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<p>9. The Institution must take such actions as necessary to manage FCOIs, including any FCOI of a subrecipient Investigator. Management of an identified FCOI requires development and implementation of a management plan and, if necessary, a retrospective review and mitigation report.</p> <p>10. The Institution must maintain records relating to all Investigator disclosures of financial interests and the Institution's review of, and response to, such disclosures and all actions under this policy or retrospective review, for at least three years from the date the final expenditures report is submitted to the PHS.</p> <p>11. The Institution must utilize enforcement mechanisms as seen appropriate and provide for employee sanctions or other administrative actions to ensure Investigator compliance as appropriate.</p> <p>12. The Institution must make application 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.</p> <p><b>SECTION II: Reporting Significant Financial Interests (SFIs) and Their Determination of Being Financial Conflicts of Interests (FCOIs)</b></p> <p>1. Prior to the Institution's expenditure of any funds under a PHS-funded research project, the Institution shall provide to the PHS Awarding Component an FCOI report regarding any Investigator's SFI found by the Institution to be an FCOI and ensure that the Institution has implemented a management plan. In cases in which the Institution identifies an FCOI and eliminates it prior to the expenditure of PHS-awarded funds, the Institution shall not submit that on an FCOI Report to the PHS Awarding Component.</p> <p>2. For any SFI that the Institution identifies as an FCOI subsequent to the Institution's initial FCOI Report during an ongoing PHS-funded research project (e.g., upon the participation of an Investigator who is new to the research project), the Institution shall provide to the PHS Awarding Component, within 60 days of determination of the FCOI, an FCOI Report regarding the FCOI and ensure that the Institution has implemented a management plan in accordance with this policy.</p> <p>3. Any FCOI Report 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 the Institution's management plan. Elements of the FCOI Report shall include (as required by the PHS Awarding Agency), but are not necessarily limited to, the following:</p> <ul style="list-style-type: none"> <li>(a) Project number;</li> <li>(b) PD/PI or Contact PD/PI if a multiple PD/PI model is used;</li> </ul>
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<p>(c) Name of the Investigator with the FCOI;</p> <p>(d) Name of the entity with which the Investigator has an FCOI;</p> <p>(e) Nature of the financial interest (e.g., equity, consulting fee, travel reimbursement, honorarium) Note: for travel, this must include the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration;</p> <p>(f) Value of the financial interest (dollar ranges are permissible: \$0-\$4,999; \$5,000-\$9,999; \$10,000-\$19,999; amounts between \$20,000-\$100,000 by increments of \$20,000; amounts above \$100,000 by increments of \$50,000), or a statement that the interest is one whose value cannot be readily determined through reference to public prices or other reasonable measures of fair market value;</p> <p>(g) A description of how the financial interest relates to the PHS-funded research and the basis for the Institution's determination that the financial interest conflicts with such research; and</p> <p>(h) A description of the key elements of the Institution's management plan, including:</p> <ol style="list-style-type: none"> <li>1) Role and principal duties of the conflicted Investigator in the research project;</li> <li>2) Conditions of the management plan;</li> <li>3) How the management plan is designed to safeguard objectivity in the research project;</li> <li>4) Confirmation of the Investigator's agreement to the management plan;</li> <li>5) How the management plan will be monitored to ensure Investigator compliance; and</li> <li>6) Other information as needed.</li> </ol> <p>4. For any FCOI previously reported by the Institution with regard to an ongoing PHS-funded research project, the Institution will 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 FCOI is still being managed or explain why the FCOI no longer exists. The Institution 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.</p> <p>5. To ensure consistency in reporting, if the Institution is a hospital facility, all copies of SFIs should be sent to the Pharmacy &amp; Therapeutics (P&amp;T) Committee consistent with their policies on reporting conflicts. If the Institution is a surgery center, copies of these SFIs should be sent to the Medical Executive Committee consistent with their policies on reporting conflicts.</p> <p><b>SECTION III: Management of Financial Conflicts of Interests</b></p> <ol style="list-style-type: none"> <li>1. Prior to the Institution's expenditure of any funds under a PHS-funded research project, the designated official(s) of an Institution shall (i) review all Investigator disclosures of Significant Financial Interests; (ii) determine whether any SFI relate to PHS-funded</li> </ol>
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<p>research; (iii) determine whether an FCOI exists; and, if so, (iv) 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:</p> <ul style="list-style-type: none"> <li>(a) Public disclosure of FCOI (e.g., when presenting or publishing the research);</li> <li>(b) For prospective research projects involving the consenting of human subjects, disclosure of the FCOI directly to participants;</li> <li>(c) Appointment of an independent monitor capable of taking measures to protect the design, conduct, and reporting of the research against bias resulting from the financial conflict of interest;</li> <li>(d) Modification of the research plan;</li> <li>(e) Change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the research (e.g., having an independent person obtain informed consent from participants);</li> <li>(f) Reduction or elimination of the financial interest (e.g., sale of the equity interest); or</li> <li>(g) Severance of relationships that create financial conflicts.</li> </ul> <ol style="list-style-type: none"> <li>2. The Institution will monitor the Investigator's compliance with the management plan on an ongoing basis until the completion of the PHS-funded research project.</li> <li>3. Prior to the Institution's expenditure of any funds under a PHS-funded research project, the institution shall ensure public accessibility, via a publicly accessible Web site or written response to any requestor within five business days of a request, of information concerning any SFI disclosed to the institution that meets the following three criteria: <ul style="list-style-type: none"> <li>(a) The SFI interest was disclosed and is still held by the senior/key personnel;</li> <li>(b) The Institution determines that the SFI is related to the PHS-funded research; and</li> <li>(c) The Institution determines that the significant financial interest is an FCOI.</li> </ul> </li> <li>4. The information that the Institution makes available via a Web site or written response to any requestor within five business days of a request will include the following: <ul style="list-style-type: none"> <li>(a) The Investigator's name;</li> <li>(b) The Investigator's title and role with respect to the research project;</li> <li>(c) The name of the entity in which the SFI is held;</li> <li>(d) The nature of the SFI; and</li> <li>(e) The approximate dollar value of the SFI, 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.</li> </ul> </li> <li>5. If the Institution uses a public Web site the information that the Institution posts shall be updated at least annually. In addition, the Institution shall update the Web site within 60 days of the Institution'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 an SFI of senior/key personnel new to</li> </ol>
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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 annually and within 60 days of the Institution's identification of a new FCOI. If the Institution responds to written requests for disclosures, the Institution will note in its written response that the information provided is current as of the date of the correspondence and is subject to updates at least annually and within 60 days of the Institution's identification of a new FCOI, which should be requested subsequently by the requestor.

6. The Institution shall have information concerning the SFIs of an individual available, for responses to written requests or for posting via the Institution's publicly accessible Web site for at least three years from the date that the information was most recently updated.

#### **SECTION IV: Managing Subrecipients**

1. If the Institution carries out the PHS-funded research through a subrecipient (e.g., subcontractors or consortium members), the Institution must incorporate as part of a written agreement with the subrecipient terms that establish whether this policy or the subrecipient's FCOI policy will apply to the subrecipient's Investigators.
2. If the subrecipient's Investigators abide by subrecipient's FCOI policy, the agreement needs to specify the time period(s) in which the subrecipient reports all identified FCOI to this Institution. The time period(s) shall be sufficient to allow the Institution to provide timely FCOI Reports, as needed, to PHS as required.
3. Alternatively, if the subrecipient's Investigators comply with the Institution's FCOI policy, the agreement must specify time period(s) to submit all disclosure of SFIs to this Institution. This time period must be timely, to allow the Institution to comply with its review, management, and reporting obligations.
4. Prior to the expenditure of funds, FCOI reports must be provided to the PHS Awarding Component regarding all Financial Conflicts of Interest of all subrecipient Investigators.

#### **SECTION V: Retrospective Review**

1. Whenever (i) an FCOI is not identified or managed in a timely manner (including failure by the Investigator to disclose an SFI that is determined by the Institution to constitute an FCOI; (2) failure by the Institution to review or manage such a financial conflict of interest; or (iii) failure by the Investigator to comply with an FCOI management plan, the designated official shall, within 120 days of the Institution's determination of noncompliance, 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.



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2. The Institution must document the retrospective review. Such documentation shall include, but not necessarily be limited to, all of the following key elements:
  - (a) Project number;
  - (b) Project title;
  - (c) PD/PI or contact PD/PI if a multiple PD/PI model is used;
  - (d) Name of the Investigator with the FCOI;
  - (e) Name of the entity with which the Investigator has a financial conflict of interest;
  - (f) Reason(s) for the retrospective review;
  - (g) Detailed methodology used for the retrospective review (e.g., methodology of the review process, composition of the review panel, documents reviewed);
  - (h) Findings of the review; and
  - (i) Conclusions of the review.
  
3. Based on the results of the retrospective review, 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 due to failure to comply with this policy, 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 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. Thereafter, the Institution will continue to submit FCOI reports annually. 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 the Institution's retrospective review.
  
4. When an FCOI report involves an SFI that was not disclosed timely by an Investigator or, for whatever reason was not previously reviewed or managed by the Institution (e.g., was not timely reviewed or reported by a subrecipient), the Institution 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 FCOI was biased in the design, conduct, or reporting of research.

**REFERENCES:**

1. 42 CFR 50
2. [http://grants.nih.gov/grants/policy/coi/coi\\_faqs.htm](http://grants.nih.gov/grants/policy/coi/coi_faqs.htm)
3. ATTACHMENT I: General Process Flowchart

**ATTACHMENT I: General Process Flowchart**

