



Shepherd Center

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Financial Conflicts of Interest in Research - AC.RES.01.12

Title: Financial Conflicts of Interest in Research, AC.RES.01.12

Purpose:

To comply with federal regulations pertaining to Financial Conflicts of Interest in government-funded research.

Summary:

This 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), National Institute of Health (NIH), National Science Foundation (NSF) grants or cooperative agreements will be free from bias resulting from Investigator financial conflicts of interest. The policy further provides a mechanism for all conflicts of interest for each award to be managed, reduced, or eliminated.

Definitions:

Financial conflict of interest (FCOI) in research: A significant financial interest that could directly and significantly affect the design, conduct, or reporting of PHS-funded research. Financial conflicts of interest in research may occur when outside financial interests compromise, or have the appearance of compromising, the professional judgment of a researcher when designing, conducting, or reporting research.

Financial interest: Anything of monetary value, whether the value is readily ascertainable.

HHS: The United States Department of Health and Human Services, and any components of the Department to which the authority involved may be delegated.

Investigator: Investigators are all persons, regardless of title or position, who are responsible designing, conducting, or reporting research funded by the PHS, NIH, or NSF, including collaborators or consultants.

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).

Research: A systematic investigation, study or experiment designed to develop or contribute to generalizable knowledge. 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, training grant, program project, or research resources award.

Significant financial interest (SFI):

- a. 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 Shepherd Center responsibilities:
 - i. 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;
 - ii. 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
 - iii. Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.
- b. 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 Shepherd Center 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.
- c. The term *significant financial interest* does not include the following types of financial interests: salary, royalties, or other remuneration paid by Shepherd Center to the Investigator if

the Investigator is currently employed or otherwise appointed, including intellectual property rights assigned to the Shepherd Center 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 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.

Standard:

Applicability: This policy applies to all persons, regardless of title or position, who are responsible for designing, conducting, or reporting research funded by the PHS/NIH/NSF, including collaborators or consultants.

Grants Manager will:

1. Inform each investigator of the Shepherd Center's FCOI policy, investigator's disclosure responsibility and Federal regulation prior to applying to a federal funding agency.
2. Serve as the Designated Institutional Official (DIO) to solicit and review disclosures of significant financial interests (SFIs) from each Investigator who is planning to participate in, or is participating in, the PHS/NIH/NSF-funded research.

Investigator(s) will:

1. Complete FCOI training prior to engaging in research related to any PHS/NIH-funded grant.
2. Complete FCOI training every 4 years thereafter.
3. Complete FCOI training immediately if Shepherd Center revises its FCOI policy that affects requirements of investigators, an investigator is new to the Shepherd Center, and/or an investigator is not in compliance with the policy or management plan.
4. Disclose any significant financial interests (SFIs) and those of the Investigator's spouse and dependent:
 - a. at time of submission,
 - b. annually during the period of the award, and
 - c. within 30 days of any new financial conflict of interest that arises during the period of the award.

Subrecipient Research or Engaging Others as Subrecipients:

1. When Shepherd Center serves as the Awardee Institution in PHS/NIH/NSF-funded research projects, Shepherd Center may require subrecipients to comply with Shepherd Center's finFCOI policy.
2. In these cases, the Awardee Institution or subrecipient and Shepherd Center will incorporate, in

a written agreement, whether the FCOI policy of the awardee entity or that of the subrecipient will apply to the subrecipient's Investigators.

3. 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 applicable law. If the subrecipient cannot provide such certification, the agreement shall state that subrecipient Investigators are subject to the FCOI policy of the awardee entity for disclosing significant financial interests that are directly related to the subrecipient's work for the Awardee Institution.
4. Additionally, if the subrecipient's Investigators must comply with the subrecipient's FCOI policy, the agreement referenced above shall specify time(s) for the subrecipient to report all identified financial conflicts of interest 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 law. 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 significant financial interests to the Awardee Institution. Such time shall be sufficient to enable the Awardee Institution to comply timely with its review, management, and reporting obligations under the law.

If Significant Financial Interests are Identified:

1. The Grants Manager will notify:
 - a. the Investigator's Department Director,
 - b. the Investigator's Department Director's designee,
 - c. the Chief Compliance Officer.
 - d. These individuals will form the **Conflict of Interest Review Committee (hereafter the "Review Committee")**. The Review Committee will serve as designated officials and choose its own chairperson.
2. The Review Committee will:
 - a. Determine whether an Investigator's SFIs is related to a PHS/NIH/NSF-funded research project and, if so related, whether the SFIs is a FCOI.
 - b. Review all the Investigator's SFI disclosures, solicit written statements from all concerned parties, evaluate all available evidence, and
 - c. Issue a report to the Chief Executive Officer (CEO).
3. The CEO will:
 - a. Evaluate the Review Committee's report, and
 - b. Make the final decision.
4. Determination Definitions:
 - a. **Relatedness:** An Investigator's significant financial interest is related to PHS/NIH/NSF-funded research when Shepherd Center, through its designated officials, reasonably determines that the SFI could be affected by the PHS/NIH/NSF-funded research; or is in an entity whose financial interest could be affected by the research.

- b. **FCOI:** A financial conflict of interest exists when Shepherd Center, through its designated officials, reasonably determines that the significant financial interest could directly and significantly affect the design, conduct, or reporting of the PHS/NIH/NSF-funded research.

If a Financial Conflict of Interest is Identified:

1. The Review Committee will take actions as necessary to manage the FCOI.
2. Management of an identified FCOI requires development and implementation of a management plan and, if necessary, a retrospective review and mitigation report pursuant to 42 CFR 50.605(a).
3. Additionally, the Review Committee must comply with, and provide, initial and ongoing FCOI reports to the PHS as required pursuant to 42 CFR 50.605(b).
4. The Review Committee must maintain records relating to all Investigator disclosures of financial interests and the Shepherd Center's review of, and response to, such disclosures (whether or not a disclosure resulted in the determination of a FCOI) and all actions under Shepherd Center'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.

Management of Financial Conflicts of Interest:

1. The Review Committee will develop and implement a management plan that specifies the actions that have been, and shall be, taken to manage FCOIs when they arise.
2. The following examples are conditions or restrictions that may be imposed by the Review Committee to manage a FCOI, but they are not limited to:
 - a. Public disclosure of FCOI (e.g., when presenting or publishing the research);
 - b. For research projects involving human subjects research, disclosure of FCOI directly to participants;
 - 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 FCOI;
 - d. Modification of the research plan;
 - e. Change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the research;
 - f. Reduction or elimination of the financial interest (e.g., sale of an equity interest); or
 - g. Severance of relationships that create financial conflicts.

Penalties and Enforcement:

1. Shepherd Center maintains the right to impose sanctions or take other administrative actions where appropriate on Investigators for failure to disclose significant financial interests and for failure to abide by this policy.
2. Sanctions may include:
 - a. Restrictions on future submission of research proposals, and

- b. Other disciplinary actions up to and including dismissal.
3. Investigators may appeal any sanction or disciplinary action(s) using the general employee grievance procedure.

Confidentiality:

1. Except to the extent required by law and federal regulations, the information disclosed throughout these processes will be kept confidential.
2. Shepherd Center is required to report the existence of real or potential conflicts of interest to certain federal agencies.

Reporting Financial Conflicts of Interest:

1. Prior to expenditure of any funds under a PHS-funded research project, Shepherd Center will, consistent with §50.604(f):
 - a. Review all Investigator disclosures of significant financial interest;
 - b. Determine whether any significant financial interests relate to PHS-funded research;
 - c. Determine whether a FCOI exists; and, if so,
 - d. Develop and implement a management plan that shall specify the actions that have been, and shall be, taken to manage such FCOI.
2. If during an ongoing PHS-funded research project, an Investigator new to the research project discloses a significant financial interest or an existing Investigator discloses a new significant financial interest to the Shepherd Center, the Review Committee will:
 - a. Review all Investigator disclosures of significant financial interest within sixty days;
 - b. Determine whether any significant financial interests relate to PHS-funded research;
 - c. Determine whether a FCOI exists; and, if so,
 - d. Develop and implement a management plan that specifies the actions that have been, and shall be, taken to manage such FCOI.
3. Whenever a FCOI is not identified or managed in a timely manner including: failure by the Investigator to disclose a significant financial interest that is determined by Shepherd Center to constitute a FCOI; failure by Shepherd Center to review or manage such a FCOI; or failure by the Investigator to comply with a FCOI management plan, Shepherd Center will, within 120 days of the Shepherd Center's determination of noncompliance:
 - a. Complete a retrospective review of the Investigator's activities and the PHS-funded research project
 - b. 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.
4. Shepherd Center will document the retrospective review including, but not necessarily be limited to, all 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 FCOI;
- 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.

Results:

1. Based on the results of the retrospective review, Shepherd Center will:
 - a. Update the previously submitted FCOI report, specifying the actions that will be taken to manage the FCOI going forward.
 - b. If bias is found, notify the PHS Awarding Component promptly and submit a mitigation report to the PHS Awarding Component.
 - i. 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 Shepherd Center'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).
 - ii. Thereafter, Shepherd Center will submit FCOI reports annually, as specified elsewhere in the policy.
2. Depending on the nature of the FCOI, Shepherd Center 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 Shepherd Center's retrospective review.
3. When Shepherd Center implements a management plan pursuant to this policy, Shepherd Center will monitor Investigator compliance with the management plan on an ongoing basis until the completion of the PHS-funded research project.
4. Prior to Shepherd Center's expenditure of any funds under a PHS-funded research project, Shepherd Center will ensure public accessibility, via a written response to **any requestor within five business days of a request**, of information concerning any SFIs disclosed to the Shepherd Center that meets the following three criteria:
 - a. The SFI was disclosed and is still held by the senior/key personnel;
 - b. Shepherd Center determines that the SFI is related to the PHS-funded research; and
 - c. Shepherd Center determines that the SFI is a FCOI.

Response to Public Inquiry:

1. The Shepherd Center FCOI policy will be posted on Shepherd Center's public website.
2. The website will contain contact information for public inquiries regarding FCOI.
3. The Vice President of Research & Innovation will provide a written response to any requestor within five business days.
4. The following information will be included in response to public inquiries:
 - a. Investigator's name;
 - b. Investigator's title and role with respect to the research project;
 - c. Name of the entity in which the significant financial interest is held;
 - d. Nature of the significant financial interest; and
 - e. Approximate dollar value of the significant financial interest (the Following dollar ranges will be used: \$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
 - f. 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
 - g. Statement 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 the Shepherd Center's identification of a new financial conflict of interest, which should be requested subsequently by the requestor."
5. Website content will be updated as needed.

Additional Reporting Requirements

1. Prior to the expenditure of any funds under a PHS-funded research project, Shepherd Center will provide to the PHS Awarding Component an FCOI report regarding any Investigator's significant financial interest found by the Shepherd Center to be conflicting and ensure that the Shepherd Center has implemented a management plan in accordance with this subpart.
2. In cases in which Shepherd Center identifies a FCOI and eliminates it prior to the expenditure of PHS-awarded funds, Shepherd Center will not submit an FCOI report to the PHS Awarding Component.
3. For any SFI that Shepherd Center identifies as conflicting subsequent to Shepherd Center'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), Shepherd Center will provide to the PHS Awarding Component, within sixty days, an FCOI report regarding the FCOI and ensure that Shepherd Center has implemented a management plan in accordance with this subpart.
4. Where such FCOI report involves a SFI that was not disclosed timely by an Investigator or, for whatever reason, was not previously reviewed or managed by Shepherd Center (e.g., was not timely reviewed or reported by a subrecipient), Shepherd Center will 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, Shepherd Center

will notify the PHS Awarding Component promptly and submit a mitigation report to the PHS Awarding Component.

5. Any FCOI report required under this policy 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 Shepherd Center's management plan.
6. Elements of the FCOI report shall include, but are not necessarily limited to the following:
 - a. Project number;
 - b. PD/PI or Contact PD/PI if a multiple PD/PI model is used;
 - c. Name of the Investigator with the FCOI;
 - d. Name of the entity with which the Investigator has a FCOI;
 - e. Nature of the financial interest (e.g., equity, consulting fee, travel reimbursement, honorarium);
 - f. Value of the financial interest (dollar ranges will be used: \$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;
 - g. A description of how the financial interest relates to the PHS-funded research and the basis for Shepherd Center's determination that the financial interest conflicts with such research; and

A description of the key elements of Shepherd Center's management plan, including: (A) Role and principal duties of the conflicted Investigator in the research project; (B) Conditions of the management plan; (C) How the management plan is designed to safeguard objectivity in the research project; (D) Confirmation of the Investigator's agreement to the management plan; (E) How the management plan will be monitored to ensure Investigator compliance; and (F) Other information as needed.

Annual Reporting:

1. For any FCOI previously reported by Shepherd Center about an ongoing PHS-funded research project, Shepherd Center will:
 - a. 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.
 - b. Specify whether the FCOI is still being managed or explain why the FCOI no longer exists.
2. Shepherd Center 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.

References:

1. 42 CFR Part 50

2. NIH Grants Policy Statement (GPS 4.1.10)
3. 2011 Public Health Service (PHS) Regulations
4. National Institute of Health Financial Conflict of Interest FAQ (Financial Conflicts of Interest in Research)

Appendices:

- a. **Sample Intranet FCOI Script**
- b. **Sample FCOI in Research Disclosure Form**
- c. **Sample Website FCOI in Research Script**