



Policy and Procedure No. 319

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Approved by: Sarah Rosen Wartell

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Personnel Policies and Procedures

Subject: Financial Conflict of Interest Policy in U.S. Public Health Services Funded Research, #319

Purpose

The Urban Institute has developed the Financial Conflict of Interest Policy (FCOI Policy) #319 to comply with the requirements in [42 CFR Part 50 Subpart F](#), and in [45 CFR part 94](#), which promotes objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct, and reporting of research funded under U.S. Public Health Service (PHS) grants and cooperative agreements or contracts, respectively, will be free from bias resulting from Investigator financial conflicts of interest.

Urban is required to create and enforce policy outlining the procedures for implementing the PHS FCOI regulation and to inform Investigators of this CFR Part; of Urban's FCOI Policy; and of the Investigator's disclosure responsibilities under the regulation and the policy. Urban is also responsible for managing identified conflicts, and reporting identified conflicts to the PHS Awarding Agency. Employees are responsible for complying with Urban's FCOI Policy for disclosing their significant financial interests to Urban.

Applicability

This policy pertaining to conflicts with the interests of Federal award Agencies is applicable to Investigators, as defined below, involved in proposed or awarded research funding from any of the PHS Agencies.

All Urban employees remain subject to Urban's Standards of Ethical Conduct Policy (#315). The FCOI Policy is supplemental for those employees who are Investigators on PHS-Funded Research projects.

Definitions

As stated in the CFR, the following definitions apply:

[Disclosure of significant financial interests](#) refers to Investigator's disclosure of significant financial interests to an Institution.

[Financial conflict of interest \(FCOI\)](#) means a significant financial interest that could directly and significantly affect the design, conduct, or reporting of PHS-funded research.

FCOI report means Urban's report of a financial conflict of interest to a PHS Awarding Agency.

Financial interest means anything of monetary value, regardless if the value is readily ascertainable.

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

Institutional Responsibilities an Investigator's professional responsibilities for which such Investigator was hired and which are conducted at or undertaken on behalf of Urban, which may include, but is not limited to, activities such as research, research consultation, teaching, outreach/extension, professional practice, institutional committee memberships and service on panels.

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 actions taken 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.

Management Plan: A plan to Manage a Financial Conflict of Interest.

PD/PI means a project director (PD) or principal Investigator (PI) 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 U.S. 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 Agency means the organizational unit of the PHS that funds the research that is subject to this subpart.

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

Research means a systematic investigation, study or experiment designed to develop or contribute to generalizable knowledge relating broadly to public health, including behavioral and social-sciences research. The term encompasses basic and applied research (e.g., a published article, book or book chapter) and product development (e.g., a diagnostic test or drug). As used in this subpart, the term includes any such activity for which research funding is available from a PHS Awarding Component through a grant or cooperative agreement, whether authorized under the PHS Act or other statutory authority, such as a research grant, career development award, center grant, individual fellowship award, infrastructure award, institutional training grant, program project, or research resources award.

Senior/key personnel means the PD/PI and any other person identified as senior/key personnel by the Institution in the grant application, progress report, or any other report submitted to the PHS by the Institution under this subpart.

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 or domestic partner and dependent children) that reasonably appears to be related to the Investigator's institutional responsibilities:
 - a. 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;
 - b. 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
 - c. Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.
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; 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 disclosure of reimbursed or sponsored travel must include:

- the purpose of the trip;
- the identity of the sponsor/organizer;
- the destination; and
- the duration of the trip.

The term significant financial interest does NOT include the following types of financial interests:

- salary, royalties, or other remuneration paid by Urban to the Investigator if the Investigator is currently employed or otherwise appointed by Urban, including intellectual property rights assigned to Urban 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;

- 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.

Training

Each Investigator planning to participate in, or who are participating in, PHS-Funded Research are required to complete training related to FCOI, regardless if a FCOI exists. Financial Conflict of Interest Committee members and the Research Integrity Officer (ROI) will also be required to complete training related to FCOI, regardless if a FCOI exists. This training is not required for Urban staff who are not participating and do not plan to participate in PHS-Funded research unless they are involved in the FCOI policy review process (ROI and FCOI Committee members). Training must be completed in the following circumstances:

- Prior to engaging in PHS-Funded Research or conducting a review as the ROI or the FCOI Committee;
- At least every four (4) years;
- If an Investigator is new to Urban, within the sixty (60) days of commencement of employment (but not later than the beginning of PHS-Funded Research by the Investigator);
- If there are revisions to the FCOI Policy or procedures in any manner that affects the requirements of Investigator;
- Urban finds that an Investigator is non-compliant with the FCOI Policy or Management Plan.

Training, or access to training, shall be provided by Urban and shall include information regarding the FCOI Policy, PHS regulations, and the Investigator's responsibilities under the FCOI Policy and the PHS Regulations to disclose Significant Financial Interests of the Investigator (and of the Investigator's spouse and dependent children).

Disclosure

Investigators are required to disclose all SFI (and those of the Investigator's spouse or domestic partner and dependent children) that reasonably appear to be related to their Institutional Responsibilities OR if no such SFI exists. The Investigator shall disclose as follows:

At time of Application

Each Investigator, including a subrecipient Investigator, if applicable, planning to participate in PHS-Funded Research must disclose if an SFI exists or certify a SFI does not exist by submitting a Financial Conflict of Interest Disclosure Form to the Research Integrity Officer (RIO) [Senior Vice President of Research] prior to submission of an application for PHS-Funded Research.

Updates

Annual: Each Investigator, including a subrecipient Investigator, if applicable, must submit an updated Financial Conflict of Interest Disclosure Form at least annually, during the period of the award, beginning with the anniversary date of the award.

The annual disclosure shall include: (a) any new information that was not disclosed to the RIO either initially or subsequently (e.g. any FCOI identified on a PHS-Funded Research project that was transferred from another institution); and (b) updated information regarding any previously disclosed Significant Financial Interest (e.g., the updated value of a previously disclosed equity interest).

Annual updates shall be required of all Investigators participating in a PHS-Funded Research project, regardless of whether an SFI was previously disclosed.

Within 30 days: Each Investigator, including a subrecipient Investigator, if applicable, must disclose a SFI by submitting an updated Financial Conflict of Interest Disclosure Form to the RIO within thirty days of discovering or acquiring (e.g., through purchase, marriage/domestic partnership, or inheritance) a new SFI.

Review

Prior to Urban's expenditure of any funds under a PHS-Funded Research project, the RIO will review all Financial Conflict of Interest Disclosure Forms and determinations shall be made, as applicable, and consistent with the FCOI Policy and PHS regulations. The RIO shall determine with reasonable discretion, whether any SFI is related to PHS-Funded Research. An SFI is related to PHS-Funded Research if (as reasonably determined by the RIO):

- the SFI could be affected by the PHS-Funded Research; or
- the SFI is in an entity whose financial interest could be affected by the PHS-Funded Research.

If the SFI is related to PHS-Funded Research, the RIO, shall then determine, with reasonable discretion, whether a FCOI exists.

- A FCOI exists if the SFI could directly and significantly affect the design, conduct, or reporting of PHS-Funded Research.

The RIO may refer the matter to the Financial Conflict of Interest Committee to conduct any review and/or determination regarding whether an SFI is related to PHS-Funded Research and/or whether a FCOI exists.

The RIO (or designated Committee) may involve the Investigator, the relevant Research Vice President, and others, as provided herein, in the determination of whether an SFI is related to PHS-Funded Research and/or whether a FCOI exists.

If it is determined that (a) an SFI is related to PHS-Funded Research and (b) an FCOI exists, the RIO shall communicate the determination to the Investigator and the relevant Research Vice President.

If the RIO and other relevant parties cannot agree on a satisfactory determination of the matter giving rise to the conflict or if the matter is, in the reasonable judgment of any one of them, significant, any one of them may refer the matter to a Leadership Committee comprised of the Executive Office, VP of Human Resources, VP Controller and Assistant Treasurer, or the designee of any one of them. Any one of these individuals may refer the matter to the Audit Committee for final resolution. If the affected individual is a Vice President, that person shall recuse themselves from the discussions, and the matter shall go directly to the President, or their designee, and may be referred to the Audit Committee.

Management of FCOIs (Management Plan)

If an FCOI has been identified, the RIO and Center Vice President will work with the Investigator to implement a Management Plan to manage, reduce, or eliminate any actual or potential FCOI presented by an SFI within 60 days. Possible approaches include, but are not limited to the following:

- Public disclosure of significant financial interests;
- Appointment of independent monitor(s) capable of taking measures to protect the design, conduct, and reporting of the research against bias resulting from the FCOI;
- Modification of the research plan;
- Change of personnel or personnel responsibilities or disqualification of personnel from participation in all or a portion of the related project or research;
- Reduction or elimination of the significant financial interest (e.g., sale of an equity interest); or
- Severance of relationships that create actual or potential financial conflicts.

Retrospective Review:

Whenever an FCOI is not identified or managed in a timely manner including:

- Investigator failure to disclose within 30 days an SFI that is determined to constitute an FCOI;
- Urban failure to review or manage an FCOI within sixty days; or
- Failure by the Investigator to comply with a FCOI Management Plan.

Urban shall, within 120 days of the determination of noncompliance, complete a retrospective review of the Investigator's activities and the research project to determine whether any research, or portion thereof, conducted during the time period of the noncompliance, was biased in the design, conduct, or reporting of such research. Urban shall document this retrospective review.

Such documentation shall include, but not necessarily be limited to, the following key elements:

- Project number;
- Project title;
- PD/PI;
- Name of the Investigator with the FCOI;
- Name of the entity with which the Investigator has a financial conflict of interest;
- Reason(s) for the retrospective review;
- Detailed methodology used for the retrospective review (e.g., methodology of the review process, composition of the review panel, documents reviewed);
- Findings of the review; and
- Conclusions of the review.

Based on the results of the retrospective review, if appropriate, Urban shall update the previously submitted FCOI report to the appropriate PHS Agency, specifying the actions that will be taken to manage the financial conflict of interest going forward.

Reporting

Urban must report FCOIs to PHS.

Content: For all PHS-Funded Research projects and prior to expenditure of any funds under the award, Urban is required to report to the PHS Awarding Agency the existence of an FCOI and submit an FCOI report.

Timing: Urban is responsible for submitting FCOI reports to the PHS Award Agency:

- Initially (prior to expenditure of PHS-Funded Research);
- Within 60 days of any subsequently identified FCOI following the initial FCOI report during an ongoing PHS-Funded Research project (e.g. upon the participation of an Investigator who is new to the PHS-Funded Research project); and
- Annually during the award period.

Annual FCOI Reports: For any FCOI previously reported by Urban with regard to an ongoing PHS-Funded Research project, Urban shall provide to the PHS Awarding Agency 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 shall specify whether the FCOI is still being managed or explain why the FCOI no longer exists. Urban shall provide annual FCOI reports to the PHS Awarding Agency for the duration of the project period (including extensions with or without funds) in the time and manner specifically specified by the PHS Awarding Agency.

Resolution of FCOI disputes

In situations where disputes arise around an Investigator's FCOI (whether FCOI was disclosed or undisclosed to Urban by the Investigator), such disputes will be referred to the Financial Conflict of Interest Committee. Depending on nature, circumstances, and value of FCOI in dispute, the Committee may refer disputes to Urban's Executive Office or to Urban's Office of Human Resources.

Public Accessibility of FCOI Policy and FCOI Information

Urban's Financial Conflict of Interest Policy in PHS-Funded Research publicly available via this web site: www.urban.org.

Urban will make information available concerning identified PHS-related FCOIs involving Senior/Key Personnel FCOIs via written response to any requestor within 5 business days of a request made to FCOI@urban.org.

Urban will update such information as specified by the PHS requirements. This information will include:

- Name of the Investigator,
- Investigator's title and role with respect to the research project,
- Name of the entity in which the SFI is held,
- The nature of the SFI, and
- 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 process or other reasonable measures of fair market value.

Subawards

Urban will take reasonable steps to ensure that subawardee Investigators comply with the FCOI regulation. For PHS-Funded Research, Urban will incorporate in a written agreement with any subawardee terms that establish whether Urban's FCOI Policy or the subawardee's FCOI policy will apply. If the subawardee Investigator(s) must comply with the subawardee's FCOI policy, the subawardee must certify as part of the agreement with Urban that its FCOI policy complies with the PHS FCOI regulation. If the subawardee cannot provide such a certification, the agreement between Urban and the subawardee will state that subawardee Investigators are subject to Urban's FCOI policy for disclosing significant financial interests that are directly related to the subawardee's work for Urban.

Urban Investigators working under PHS-funded subawards: If Urban will be a subrecipient/subcontractor to another entity on a PHS award, and is asked to certify whether Urban will use its own FCOI Policy or that of the prime recipient, note that Urban does not agree to use or follow any other entity's FCOI policy, forms, or procedures and will adhere to Urban's FCOI Policy.

Record Retention

The RIO shall retain all records relating to Investigator disclosures of financial interests; the review of and response to such disclosures (whether or not a disclosure resulted in the determination of a FCOI); and all actions under this Policy or retrospective review, if applicable.

Such records shall be retained for at least four (4) years from the date of submission of final expenditure reports to PHS for each PHS-Funded Research project (or where applicable from other dates specified in the PHS Regulations for different situations).

Such records may be destroyed following the expiration of the retention period, unless there is relevant pending or active administrative or legal action or otherwise required by applicable law or Urban policy.