



*at the* UNIVERSITY of CHICAGO

## FINANCIAL CONFLICT OF INTEREST IN PHS AND NSF-FUNDED RESEARCH

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**Policy Name:** Financial Conflict of Interest  
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*Policy Guide provides general guidelines. NORC reserves the right to make changes to the Policy Guide at any time. Employment is at-will. This policy is not an implied or explicit contract or guarantee of employment.*

## I. Purpose & Scope

To establish NORC's policy regarding financial conflicts of interest in research funded by the U.S. Public Health Service (PHS) and the National Science Foundation (NSF).

In addition to [Policy C3 – Conflict of Interest](#), NORC has instituted this Financial Conflict of Interest (FCOI) Policy to satisfy the requirements of the U.S. Department of Health and Human Services (HHS) FCOI Regulation for PHS-funded research (42 CFR Part 50 and 45 CFR Part 94) and the National Science Foundation (NSF Award and Administration Guide, Chapter IV).

Consistent with 42 CFR 50.601, the PHS FCOI regulation was established to promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct, and reporting of research funded under NIH grants or cooperative agreements will be free from bias resulting from any conflicting financial interest of an Investigator.

NORC is required to create and maintain a written and enforced policy stating the procedures for implementing the PHS FCOI regulation and to inform each Investigator of the regulation, of the Institution's FCOI policy, and of the Investigator's disclosure responsibilities under the regulation and the policy. NORC is also responsible for managing, reducing, or eliminating identified conflicts, and reporting identified conflicts to the Public Health Service (PHS) Awarding Component.

Investigators are responsible for complying with NORC's written FCOI policy and for disclosing their significant financial interests to NORC.

This policy applies to all PHS Research Activities with an award issue date of August 24, 2012 or later, and to proposals for research activities submitted to PHS on or after August 24, 2012. PHS research activities that are ongoing as of August 24, 2012 will become subject to this policy as additional funds are requested through submission of a progress report, competing renewal application, proposal for supplemental funding, or through approval of a no-cost time extension. The PHS FCOI regulation does not apply to Phase I Small Business Innovative Research or Small Business Technology Transfer applications.

This policy also applies to research or educational activities funded or proposed for funding by the National Science Foundation. To the extent that other funding agencies or organizations (whether governmental or private) have adopted financial conflict of interest policies and procedures, NORC will comply with such policies and procedures when applicable.

**Sections II through X of this Policy apply only to PHS-funded research. Section XI of this Policy applies only to research and educational activities funded or proposed for funding by the NSF. Section XII applies to research funded by either PHS or NSF.**

NORC will certify in each application for PHS funding that NORC:

- has in effect an up-to-date written and enforced administrative process to identify and manage FCOIs related to all PHS research projects
- will promote and enforce Investigator compliance with the PHS FCOI regulation pertaining to disclosure of Significant Financial Interests
- will manage FCOIs and provide initial and ongoing FCOI reports to PHS

NORC designates the Financial Conflicts of Interest Compliance Officer to administer this policy. The Chief Financial Officer has overall responsibility for this policy. It is the obligation of any investigator with concerns or questions about this policy to seek guidance from NORC. E-mails with concerns or questions relating to this policy should be sent to [FCOI@norc.org](mailto:FCOI@norc.org).

## **II. Definitions Applicable to PHS-Funded Research**

As stated in 42 CFR 50.603:

**A Financial Conflict of Interest (FCOI)** is 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.

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

**Institutional Responsibilities** means an Investigator's professional responsibilities on behalf of the Institution, including, but not limited to, activities such as research, research consultation, teaching, professional practice, institutional committee memberships, and service on panels such as Institutional Review Boards or Data and Safety Monitoring Boards.

**Investigator** refers to 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, including Investigators working for subgrantees/contractors/subcontractors/collaborators. In determining who is an Investigator, NORC will consider the role, rather than the title, of those involved in research and the degree of independence with which those individuals work.

**Manage** means taking action to address an FCOI, which can include reducing or eliminating the FCOI, to ensure, to the extent possible, that the design, conduct and reporting of research will be free from bias.

**Senior/Key Personnel** means the Project Director/Principal Investigator (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 the regulation.

**Significant Financial Interest (SFI)** is defined as:

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:

(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.

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

- salary, royalties, or other remuneration paid by NORC to the Investigator if the Investigator is currently employed or otherwise appointed by NORC, including intellectual property rights assigned to NORC and agreements to share in royalties related to such rights;
- any ownership interest in NORC 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;
- 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.

### III. Training Requirements

Each Investigator, including subrecipient Investigator(s), must complete FCOI training before engaging in research related to any PHS-funded grant or contract, and at least every four years. Investigators must complete FCOI training immediately under the following circumstances:

- NORC's FCOI policies change in a manner that affects Investigator requirements
- An Investigator is new to NORC
- NORC finds an Investigator to be noncompliant with NORC's FCOI policy or management plan.

#### IV. Investigators' Disclosure Requirements

Investigators are required to disclose to NORC all of their significant financial interests (and those of the Investigator's spouse and dependent children) that reasonably appear to be related to their Institutional responsibilities:

- (1) at the time of application for PHS-funded research;
- (2) no later than thirty days from the date of discovering or acquiring (e.g., through purchase, marriage, or inheritance) a new Significant Financial Interest; and
- (3) at least annually during the period of award.

The definition of "significant financial interest" is above in the "Definitions" section of this document.

Investigators also must disclose any reimbursed or sponsored travel (that which is paid on behalf of the Investigator and not reimbursed to the Investigator) related to their Institutional responsibilities. 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.

NORC will determine if further information is needed, including a determination or disclosure of monetary value, to determine whether the travel constitutes an FCOI with PHS-funded research.

## V. Subrecipients and Other Collaborators

### A. NORC subrecipients:

Where NORC carries out PHS-funded research through subgrantees/contractors/subcontractors/collaborators, NORC will take reasonable steps to ensure that Investigators working for such entities comply with the FCOI regulation. For PHS-funded research, NORC will incorporate in a written agreement with any subrecipient terms that establish whether NORC's FCOI policy or the subrecipient's FCOI policy will apply to subrecipient Investigators, and will include time periods to meet disclosure and/or FCOI reporting requirements. If the subrecipient's Investigators must comply with the subrecipient's FCOI policy, the subrecipient must certify as part of the agreement with NORC that its FCOI policy complies with the PHS FCOI regulation. If the subrecipient cannot provide such a certification, the agreement between NORC and the subrecipient will state that subrecipient Investigators are subject to NORC's FCOI policy for disclosing significant financial interests that are directly related to the subrecipient's work for NORC. Please see 42 CFR Section 50.604(a) for grants and cooperative agreements and 45 CFR Part 94.4(a) for contracts. With respect to grants or cooperative agreements, this arrangement should be defined in a formal written agreement with each consortium participant.

B. NORC investigators who receive PHS subawards: If NORC will be a subrecipient/subcontractor to another entity on a PHS award/contract, a NORC investigator or department may receive a form from the prime grantee/contractor asking NORC to certify whether NORC will use its own FCOI policy or whether NORC will use the prime recipient/contractor's policy. The answer is always that NORC uses its own FCOI policy. NORC does not agree to use or follow any other entity's FCOI policy, forms, or procedures.

## VI. Reporting of Financial Conflicts of Interest to PHS Awarding Components

For PHS awarded grants and cooperative agreements, NORC will submit all required FCOI reports to the PHS Awarding Component through the electronic Research Administration (eRA) Commons FCOI Module.

**Submission of Initial FCOI Reports:** Before NORC's expenditure of any funds under a PHS-funded research project, NORC will provide to the PHS Awarding Component an FCOI report and ensure that NORC has implemented a management plan for any FCOI. If NORC identifies an FCOI and eliminates it prior to the expenditure of PHS-awarded funds, NORC is not required to submit an FCOI report to the PHS Awarding Component.

**Submission of FCOI Reports during ongoing PHS-funded Research:** For any FCOI that NORC identifies during an ongoing PHS-funded research project (such as, upon participation of an Investigator who is new to the project, or for newly identified FCOIs for existing Investigators), NORC will provide to the PHS Awarding Component, within 60 days, an FCOI report regarding the FCOI and ensure that a management plan has been implemented.

**Annual FCOI report:** For any FCOI previously reported by NORC, NORC will provide an annual FCOI report that addresses the status of the financial interest and any changes to the management plan. Annual FCOI reports will specify whether the Financial Conflict of Interest is still being managed or explain why the FCOI no longer exists. Annual FCOI reports must be submitted to the NIH (e.g., through the eRA Commons for grants and cooperative agreements) for the duration of the project period (including extensions with or without funds) at the same time as when NORC is required to submit the annual progress report (i.e., two months prior to the start date or 45 days prior to the start date of the noncompeting continuation award), including a multi-year funded progress report, or at the time of the extension (e.g., submission of an extension notification in the eRA Commons or submission of a NIH prior approval request, whichever is applicable.) The annual FCOI report is not to be submitted as part of the annual progress report. The annual FCOI report is submitted separately through the eRA Commons FCOI Module.

All FCOI reports must include the following information:

- Grant/Contract Number,
- Project Director/Principal Investigator (PD/PI) or Contact PD/PI,
- Name of Investigator with FCOI,
- Whether FCOI was managed, reduced or eliminated,
- Name of the entity with which the Investigator has a FCOI,
- Nature of FCOI (e.g., equity, consulting fees, travel reimbursement, honoraria),
- Value of the financial interest
  1. \$0 – \$4,999
  2. \$5K – \$9,999
  3. \$10K – \$19,999
  4. Amounts between \$20K - \$100K by increments of \$20K



5. Amounts above \$100K by increments of \$50K or a statement that a value cannot be readily determined,
  - A description of how the financial interest relates to PHS-funded research and the basis for NORC's determination that the financial interest conflicts with such research,
  - Key elements of the NORC management plan, and
  - An FCOI report for any FCOIs identified for subrecipient Investigators.

## **VII. Management Plans for Financial Conflicts Of Interest**

Prior to NORC's expenditure of any funds under a PHS-funded research project, the NORC designated official(s) will review all Investigator disclosures of significant financial interests; determine whether any SFIs relate to PHS-funded research; determine whether a financial conflict of interest exists; and, if so, develop a management plan that specifies the actions that have been and will be taken to manage the financial conflict of interest.

The key elements of the management plan include:

- The role and principal duties of the conflicted Investigator in the research project
- Conditions of the management plan
- How the management plan is designed to safeguard objectivity in the research project
- Confirmation of the Investigator's agreement to the management plan
- How the management plan will be monitored to ensure Investigator compliance

Examples of conditions or restrictions that might be imposed to manage a financial conflict of interest include, but are not limited to:

- Public disclosure of financial conflicts of interest (e.g, when presenting or publishing research);
- For research projects involving human subjects research, disclosure of financial conflicts of interest directly to participants;

- 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;
- Modification of the research plan;
- Change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the research;
- Reduction or elimination of the financial interest (e.g., sale of an equity interest);
- Severance of relationships that create financial conflicts.

Updated or annual FCOI reports must include the status of the management plan (i.e., whether the financial conflict is still being managed or explain why the financial conflict no longer exists) and a description of any changes to the management plan since the last FCOI report was submitted to the PHS Awarding Component.

The NIH may, at any time, request additional information regarding all conflicting interests identified by NORC and how those interests have been managed, reduced or eliminated to protect the research from bias and may inquire into NORC's procedures and actions regarding FCOIs in research funded by NIH, including a requirement for submission, or review on site, of all records pertinent to compliance with the regulation.

### **VIII. Retrospective Review and Mitigation Reports**

Whenever a Financial Conflict of Interest is not identified or managed in a timely manner, including:

- Failure by the Investigator to disclose a Significant Financial Interest that is determined by the Institution to constitute a Financial Conflict of Interest;
- Failure by the Institution to review or manage such a Financial Conflict of Interest; or
- Failure by the Investigator to comply with a Financial Conflict of Interest management plan;

NORC will, within 120 days of NORC'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.

NORC will document the retrospective review, which will include at least the following key elements:

- Project number;
- Project title;
- PD/PI or contact PD/PI if a multiple PD/PI model is used;
- 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, etc.);
- Findings of the review; and
- Conclusions of the review.

If bias is found, NORC will notify the PHS Awarding Component promptly and submit a mitigation report to the PHS Awarding Component. The mitigation report will include, at a minimum, the key elements documented in the retrospective review above, a description of the impact of the bias on the research project, and NORC's plan of action or actions taken to eliminate or mitigate the effect of the bias (i.e., 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, NORC will submit FCOI reports annually as prescribed by the regulation.

## **IX. Public Accessibility of FCOI Policy and FCOI Information**

NORC makes its policy on Financial Conflict of Interest in PHS-Funded Research publicly available via this web site: <http://www.norc.org>

NORC will make information available concerning identified FCOIs by Senior/Key personnel by a written response to any requestor within 5 business days of a request made to FCOI@norc.org. NORC will update such information as specified by the HHS rules. This information will include:

- The name of the Investigator,
- 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 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.

In situations where NORC is working with a subrecipient, it is NORC's responsibility to make FCOI information publicly accessible. However, when the subrecipient Investigator is required to comply with the subrecipient's FCOI policy, the subrecipient Institution will also make FCOI information publicly accessible. In these situations, NORC can consider including the requirement for the subrecipient Institution to make FCOI information publicly available as part of the subaward agreement.

## **X. Implementation of Financial Conflict of Interest Requirements for PHS-Funded Research**

NORC will:

- Solicit and review SFI disclosure statements from each Investigator who is planning to participate in, or is participating in, PHS-funded research, no later than at the time of application,
- Provide guidelines to the designated official(s) to identify FCOIs,
- Establish a process to review all SFI, determine if they relate to PHS-funded research and determine if an FCOI exists, prior to NORC's expenditure of funds,

- Inform each Investigator of NORC's Policy as well as the PHS FCOI regulation,
- Inform each Investigator of his/her disclosure responsibilities and procedures for doing so,
- Provide guidelines for enforcement mechanisms and sanctions where appropriate,
- Proceed with appropriate actions to manage, reduce, or eliminate any FCOIs. Management of an FCOI requires development and implementation of a management plan,
- Complete and document a retrospective review, as necessary, and, if bias is found, develop and submit a monitoring plan and a mitigation report, pursuant to 50.605(a) and 50.605(b)(2),
- Maintain records of all financial disclosures and all actions taken by NORC with respect to each FCOI as follows:
  - (1) in the case of grants or cooperative agreements, for at least three years from the date of submission of the final expenditures report, or where applicable, from other dates specified in 45 CFR 74.53(b) for different situations;
  - (2) in the case of research contracts, for three years after final payment or, where applicable, for the other time periods specified in 48 CFR Part 4, subpart 4.7;
- Establish adequate enforcement mechanisms and provide for sanctions where appropriate;
- Certify, in each application for funding to which the regulation applies, that the Institution has a written and enforced administrative process to identify and manage, reduce, or eliminate conflicting interests with respect to all research projects for which funding is sought from the PHS;
- Prior to the time of application, require that each Investigator who is planning to participate in the research has submitted to the Institutional designated official(s) a listing of his/her known Significant Financial Interests (and those of his/her spouse and dependent children) 1) that would reasonably appear to be affected by the research for which funding is sought; and 2) in entities whose financial interest would reasonably appear to be affected by the research.
- Report the existence of any FCOI to the PHS Awarding Component accurately and in a timely manner as required by the regulation;

- Prior to the Institution's expenditure of any funds under the award must report to the PHS Awarding Component the existence of an FCOI (but not the nature of the interest or other details) found by NORC and ensure that the conflicting interest has been managed, reduced, or eliminated;
- For any FCOI that NORC identifies subsequent to the NORC's initial report under the award, NORC must report the FCOI and manage, reduce, or eliminate it, at least on an interim basis, within 60 days of that identification; and
- Make information available upon request to the NIH regarding all FCOIs identified by NORC and how those conflicting interests have been managed, reduced, or eliminated.

## **XI. Requirements for Reporting and Managing Financial Conflicts of Interest in Research funded by the National Science Foundation**

For research funded or proposed for funding by the National Science Foundation (NSF), the term "investigator" means the Principal Investigator, co-Principal Investigators, and any other person at NORC who is responsible for the design, conduct, or reporting of research or educational activities funded or proposed for funding by NSF.

For NSF-funded research, NORC has chosen to apply the definition of "Significant Financial Interest" as used in the PHS FCOI regulation, as it relates to remuneration and equity interests in publicly-traded and non-publicly traded entities, and as it relates to intellectual property rights and interests. However, unlike for PHS-funded projects, NORC is not requiring investigators on NSF-funded projects to report reimbursed or sponsored travel. See Section II of this Policy for the definition of "Significant Financial Interest."

Each NORC Investigator must disclose to NORC all Significant Financial Interests of the Investigator (including those of the investigator's spouse and dependent children) (i) that would reasonably appear to be affected by the research or educational activities funded or proposed for funding by NSF; or (ii) in entities whose financial interests would reasonably appear to be affected by such activities.

Investigators must disclose to NORC their Significant Financial Interests (SFIs) (and those of their Spouse and Dependent Children):

- (1) at the time a proposal is submitted to the National Science Foundation;
- (2) as new reportable SFIs are obtained; and
- (3) at least annually during the period of award.

A conflict of interest exists when the designated NORC official reasonably determines that a significant financial interest could directly and significantly affect the design, conduct, or reporting of NSF-funded research or educational activities.

The designated NORC official will review investigator's financial disclosures, determine whether a conflict of interest exists, and determine what conditions or restrictions, if any, should be imposed by NORC to manage, reduce, or eliminate the conflict of interest. If the designated NORC official determines that imposing conditions or restrictions would be either ineffective or inequitable, and that the potential negative impacts that may arise from a significant financial interest are outweighed by interest of scientific progress, technology transfer, or the public health and welfare, then the NORC official may allow the research to go forward without imposing such conditions or restrictions.

NORC will take reasonable steps to ensure that subawardees, contractors, or collaborators on NORC research projects have their own FCOI policies in place that meet NSF's COI policy standards or that Investigators working at those entities follow NORC's FCOI policy.

NORC investigators who receive NSF subawards: If NORC will be a subrecipient/subcontractor to another entity on an NSF award/contract, a NORC investigator or department may receive a form from the prime grantee/contractor asking NORC to certify whether NORC will use its own FCOI policy or whether NORC will use the prime recipient/contractor's policy. The answer is always that NORC uses its own FCOI policy. NORC does not agree to use or follow any other entity's FCOI policy, forms, or procedures.

NORC will use the NSF FastLane System to notify NSF of any conflict of interest that cannot be managed, reduced or eliminated.

NORC will keep NSF's Office of the General Counsel appropriately informed if NORC finds that it is unable to satisfactorily manage a conflict of interest.

NORC will maintain records of all financial disclosures and of all actions taken to resolve conflicts of interest for at least 3 years beyond the termination or completion of the grant to which they relate, or until the resolution of any NSF action involving those records, whichever is longer.

## **XII. Sanctions**

Note: this section pertains to research funded by both the Public Health Service and the National Science Foundation

Failure by an individual to comply with the terms of this policy, to file a complete and truthful financial disclosure for pending proposals, or when a new financial interest is obtained, or failure to comply with any conditions or restrictions directed or imposed, including failure to cooperate with appointed project monitoring bodies, will be grounds for discipline. Agreements with consultants who either fail to file a complete disclosure or fail to comply with any conditions or restrictions imposed may be terminated. Similarly, agreements with subrecipient organizations may be terminated if that organization fails to comply with its obligations under the PHS regulations.

In any case in which the U.S. Department of Health and Human Services determines that a PHS-funded research 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 NORC as required by the PHS regulation, NORC will require the Investigator involved to disclose the FCOI in each public presentation of the results of the research and request an addendum to previously published presentations.

**Effective date of this policy: August 24, 2012**