



THE ROSKAMP INSTITUTE, INC.

Financial Conflict of Interest Policy

February 2021

Introduction

The purpose of this policy is to document the requirements to comply with PHS regulations (42 CFR Part 50, Subpart F, Promoting Objectivity in Research; 45 CFR Part 94, Responsible Prospective Contractors). These standards intend to establish and promote the integrity of design, conduct, and reporting of any funded research grant, contracts, and/or agreements by the Public Health Service (PHS) from bias resulting from any investigator financial conflict of interest.

This policy provides guidelines to help personnel manage any personal affairs, financial activities, and/or employment outside of The Roskamp Institute, "the Institute", that may result in conflict with their responsibility and that of the Institute in complying with federal laws when participating in funded research by PHS.

Definitions

Please see the bottom of this policy for a list of all definitions and abbreviations used.

Investigator Responsibilities

It is the responsibility of all investigators applying to any PHS funding to:

- Complete FCOI training prior to engaging (submitting or participating) in any PHS research project. Please print and submit the certificate to FCOI@roskampinstitute.org.
- Complete and submit a Financial Interest Disclosure Form prior to working in any PHS-funded projects.
- If any financial conflict of interest arises, the investigator is to notify the AOR within thirty days and submit an updated a Financial Interest Disclosure Form.
- It is the PI's responsibility to ensure those with financial interests in research are identified and make the required disclosure in conjunction with submission of a research proposal.
- Any investigator who has acquired a new or increased financial interest during the course of a research project shall report it immediately to the AOR.

Sub-Recipient Responsibilities

For PHS-funded research that involves subcontractors, subgrantees or sub-awardees (collectively subrecipients) at other Institutions, The Roskamp Institute will require a written agreement that includes terms that establish whether the FCOI policy of the awardee Institution or that of the subrecipient Institution will apply to subrecipient Investigators. This agreement will specifically address time periods to meet disclosure and/or financial conflict of interest reporting requirements.

Subrecipient Institutions who rely on their Financial Conflict of Interest policy must report identified financial conflicts of interests to the awardee Institution in sufficient time to allow the awardee Institution to report the FCOI to the PHS Awarding component.

Subrecipients who do not have such a conflict of interest policy will be required to follow the Roskamp Institute FCOI in Research policy. A subrecipient's failure to promptly comply with the Roskamp Institute policy will be considered grounds for immediate termination by The Roskamp Institute of any applicable subcontract or subaward. The written agreement terms required by The Roskamp Institute

will contain a provision that subrecipients will report to The Roskamp Institute as the awardee Institution, any identified FCOI in sufficient time to allow The Roskamp Institute to report and manage the FCOI to meet the reporting obligations described above.

Company Responsibilities

It is the responsibility of the Roskamp Institute (specifically the COO and AOR):

- To provide and notify all investigators and key personnel of the required information or any revisions made to the policy.
- To record, review and maintain all Financial Interest Disclosure Forms and FCOI training certificates.
- To determine whether a FCOI exists.
- Develop and maintain a FCOI management plan for any reported FCOIs.
- Maintain FCOI policy on Institute's publicly accessible website.
- Ensure FCOI policies and training comply with federal regulations.

Review of FCOI.

The designated Research Administration staff member (Designee) conducts an initial review of all disclosures. If necessary, the Designee obtains additional information from the investigator and other individuals to help determine whether the SFI disclosed is related to a proposed or existing sponsored project or program. The Designee then formally identifies cases that require further review and refers such cases to the IO.

The IO will review the collected information and determine whether a financial conflict of interest exists by considering the following:

- Impact on integrity of research data.
- Risks to rights and safety of animal and/or human research subjects.
- Risks to the rights of students and trainees participating in research; and
- Appearance of conflict of interest.

If a financial conflict of interest is identified, the IO will determine whether the research can be undertaken with appropriate management.

Management Plan

A Management Plan may be developed by the IO and RO to ensure compliance with this policy.

The Management Plan will be developed collaboratively and may require one or more of the following actions (but not limited to) to be taken in order to manage, reduce or eliminate any actual or potential conflict of interest:

- Public disclosure of significant financial interests (e.g., when presenting or publishing the research), if appropriate.
- Disclosure of significant financial interests directly to subjects involved in human research.
- Appointment of an independent monitor capable of taking measures to protect the design, conduct, and reporting of research.
- Modification of research plan.
- Change of personnel or personnel responsibilities or disqualification 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 the actual or potential conflict of interest.
- If it proves impossible to reach an acceptable Management Plan, funds will be returned to the sponsor.

A draft Management Plan will be provided to the Investigator for review and comment before it is finalized. The Investigator and their immediate supervisor must sign the final RO-approved plan to acknowledge their agreement to comply.

If the Institution identifies a SFI that was not disclosed or reviewed in a timely manner it will initiate the review process and an interim management plan will be implemented when necessary.

Monitoring

Investigator compliance with Management Plans will be monitored by Roskamp Institute officials. The frequency of monitoring will be dictated by sponsor/agency requirements and Management Plan provisions.

Confidentially

All disclosures or information obtained in reviewing a potential FCOI is kept confidential, except where disclosure is required by federal regulations.

Enforcement

Failure on the part of an Investigator to comply with this policy will result in disciplinary action and/or sanctions which may include formal reprimand, non-renewal/termination of appointment or affiliation, additional training requirements, additional supervision, closing existing research or denying future research by the Investigator, and/or any other enforcement action mandated by the applicable funding agency or the Roskamp Institute.

Accessibility

An up to date FCOI policy will be maintained on the Institute's publicly accessible website. The Institute will inform all investigators of the policy, their responsibility as well as in the event of any revised and updated policy.

In addition, information concerning identified FCOIs held by senior/key personnel will be made available to requestors via an email response within five business days from when the Research Official receives the request. This information may be requested by calling the Roskamp Institute at (941) 752-2949 or emailing FCOI@roskampinstitute.org.

The written response will include:

- Senior/key personnel name
- Senior/key personnel's role in the research project
- Name of the entity in which the FCOI is held
- Nature of the FCOI
- Approximate dollar value of the FCOI or a statement that the value cannot be readily determined

This information will remain available for three years from the date the information was most recently updated.

Reporting

The Roskamp Institute will provide to the PHS Awarding Component a FCOI report as outlined in the regulations:

1. Initial Report: Prior to expenditure of any funds under the NIH-funded research project, the Institution will provide a FCOI report regarding any SFI found to be a FCOI. The Roskamp Institute will also provide a FCOI report within 60 calendar days from the date of a new SFI disclosure determined to be a FCOI, a new Investigator with an identified FCOI becomes engaged in the project or when the Institution identifies a FCOI not previously disclosed. This report will include the following information:
 - o Grant/Contract Number

- PD/PI
 - Name of Investigator with FCOI
 - Nature of the FCOI (e.g., equity, consulting fees, travel reimbursement or honoraria)
 - Value of the financial interest 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
 - Description of how FCOI relates to PHS-funded research and the basis for the determination that the financial interest conflicts with such research
 - Key elements of the Management Plan
2. Annual updates to this report will be submitted to the PHS Awarding Component for the duration of the research project. The annual report will include:
- Status of the FCOI
 - Changes to the Management Plan
 - Justification if FCOI no longer exists

Record Keeping

The Roskamp Institute will maintain all records related to the implementation of this policy for at least three years after:

- the date of creation.
- the date of termination or completion of a research award or contract.
- the submission of the final expenditures report; or
- the date of final resolution of any investigation, audit, or similar action involving the records.

Training Requirements

PHS-funded Investigators must complete FCOI training prior to engaging in research related to any PHS-funded grant or contract and at least every four years thereafter. Training must also be completed as soon as reasonably possible under the following circumstances:

- This policy changes in a manner that affects Investigator requirements
- An Investigator is new to the Roskamp Institute and will be working on PHS-funded research
- An Investigator is found to be noncompliant with this policy or their approved Management Plan

The required course is accessible by following this [link](#) to access the NIH FCOI training and complete the quiz at the end: [FCOI Training](#) – email certificate to: FCOI@roskampinstitute.org

Definitions

- **Authorized Organization Representative (AOR)** is a representative who submits a grant application on behalf of a company. These representatives have the authority to sign off on grant application and any other certifications and/or assurances necessary to complete the application process.
- **Research Official (RO)** means the Roskamp Institute official responsible for the implementation of this policy, including the solicitation and initial review of disclosures of significant financial interest from research Investigators.
- **Conflict of Interest Management Plan** means the written plan developed to manage conflicts by mitigating, reducing, or eliminating Financial Conflicts of Interest so that the design, conduct or reporting of research is free from bias or the appearance of bias.
- **Entity means** any domestic or foreign, public or private, entity or organization (excluding a Federal agency) from which an Investigator (and/or the Investigator's spouse and/or dependent children) receives remuneration, or in which any person has an ownership or equity interest.
- **Financial Interest** means anything of monetary value or potential monetary value held by the Investigator, the Investigator's spouse and/or dependent children whether or not the value is readily ascertainable.

- **Financial Conflict of Interest** means a Significant Financial Interest related to a research program or project that could directly and significantly affect the design, conduct or reporting of research.
- **Institution** means any domestic or foreign, public, or private, entity or organization (excluding a Federal Agency) that is applying for, or receives, PHS or NSF research funding.
- **Institutional Official (IO)** means the individual who is legally authorized to act for the institution, and on behalf of the institution.
- **Institutional Responsibilities** means an Investigator's professional responsibilities on behalf of the Roskamp Institute including, but not limited to, activities such as research, research consultation, teaching, professional/clinical practice, institutional committee memberships, and service on panels such as Institutional Animal Care and Use Committees or Institutional Biosafety Committee, etc.
- **Investigator** means the principal investigator and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research, or proposing of research, including persons who are subcontractors, collaborators, or consultants. At the Roskamp Institute this definition includes, but is not limited to, the following roles: Principal investigator, co-investigators, research coordinators, research associates, collaborators and consultants, and may include research assistants and students as identified by the PI depending on their specific roles and responsibilities.
- **Management** means actions taken to address a financial conflict of interest, which can include reducing or eliminating the financial conflict of interest, and to ensure, to the extent possible, that the design, conduct, and reporting of research will be free from bias.
- **PI** means the principal investigator of a research project.
- **Public Health Service (PHS) Awarding Component** means the organizational unit of the PHS that funds the research (e.g., National Institutes of Health).
- **Research** means a systematic investigation designed to develop or contribute to generalizable knowledge relating broadly to public health, including behavioral and social-sciences research through which an investigator collects data through intervention or interaction with animal or human subjects, or from identifiable private information. The term encompasses basic and applied research and product development. The term also includes any such activity for which research funding is available from a PHS or NSF Awarding Component through a grant or cooperative agreement, whether authorized under the PHS, NSF, or other statutory authority.
- **Senior/Key Personnel** means the Project Director/Principal Investigator 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 or NSF by the Institution under this subpart.
- **Significant Financial Interest (SFI)** means
 - A financial interest consisting of one or more of the following interests of the Investigator (and/or of the Investigator's spouse and/or dependent children) that reasonably appears to be related to the Investigator's institutional responsibilities:
 - o 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 the 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 interests includes any stock, stock option, or other ownership interest, as determined through reference to public prices or other reasonable measures of fair market value.
 - o 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 (and/or the Investigator's spouse and/or dependent children) holds any equity interest (e.g., stock, stock option, or other ownership interest); or
 - o Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.

For PHS-funded investigators, any reimbursed or sponsored travel related to an Investigator's institutional responsibilities, including that which is paid on behalf of the investigator so that the exact monetary value may not be readily available.

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

- Salary, royalties, or other remuneration paid by the Roskamp Institute to the Investigator if the Investigator is currently employed or otherwise appointed by the Roskamp Institute, including intellectual property rights assigned to the Roskamp Institute 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 agency, an Institution of higher education, 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, an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education.
- Travel by a PHS-funded Investigator that is reimbursed or sponsored by a federal, state, or local government agency, an Institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education.

Contact information

Please send any requests to FCOI@roskampinstitute.org or by calling the Roskamp Institute at (941) 752-2949.