



Policy 4.14

Responsible
Executive: Lois
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CONFLICT OF INTEREST IN RESEARCH POLICY

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Policy Statement

The purpose of this policy is to educate individuals about situations that generate conflicts of interest, and to provide means for academic staff members and the University to identify, manage, reduce, and/or eliminate actual or potential conflicts of interest. Every member of the academic community has an obligation to become familiar with, and abide by, the provisions of this policy.

The following definitions will be used to inform the policy implementation:

Investigator - This policy applies to all academic staff members who fall under the definition of Investigator. Specifically – the project director or principal Investigator, and any other persons, regardless of title or position, who are responsible for the design, conduct, or reporting of research or educational activities funded or proposed for funding. Therefore, the policy can apply to collaborators, consultants, post-doctoral fellows, graduate students, and others who meet the threshold for responsibility. See Compliance Guidance here.

Certification/Disclosure Process - All academic staff members who meet the definition of Investigator (as defined above) must provide certification of their knowledge of and compliance with this policy on an annual basis. The certification process involves either a certification of no significant financial interests or the disclosure of existing significant financial interests to the Institution. In addition to the annual requirement, the acquisition or discovery of new significant financial interests requires disclosure within 30 days. All disclosures are reviewed by the Roosevelt University's Conflict of Interest Committee (COIC).

Significant Financial Interest (SFI) - Anything of monetary value, whether the value is readily ascertainable, that 1) is related to the Investigator's professional responsibilities on behalf of the Institution; and 2) belongs to the Investigator or the Investigator's spouse or dependent children. Additional details regarding what constitutes a Significant Financial Interest are specified in Section III.

Financial Conflict of Interest (FCOI) - A significant financial interest that could directly and significantly affect the design, conduct, or reporting of research. Similarly, if a significant financial interest could reasonably appear to be affected by the research, or the interest is in entities whose financial interests would reasonably appear to be affected by the research, review and elimination or management of the conflict is required.

Institutional Responsibilities - Investigators' 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 and Data Safety Monitoring Boards. All duties referred to in the Roosevelt University Faculty Handbook (PDF) are considered Institutional Responsibilities.

Institutional Official - the individual at the Institution responsible for the solicitation and review of disclosures of significant financial interests from each Investigator who is participating in, or is planning on participating in, research. The Institutional Official for the Roosevelt University is the Director of Research and Sponsored Programs.

Reason for Policy

This policy is required to ensure compliance with federal guidelines on reporting conflicts of interest in research. It is the policy of Roosevelt University (RU, "the University") that all departments comply with this policy. Roosevelt University is committed to maintaining a research environment that promotes attention to the highest ethical standards for all sponsored and non-sponsored research. This commitment includes compliance with regulatory requirements set forth by the Public Health Service (PHS) and the National Science Foundation (NSF). It is the responsibility of the University to promote objectivity in research through the establishment of a Conflict of Interest Policy.

A conflict of interest might take various forms, but includes any circumstance where personal, professional, financial, or other private interests of a person or institution compromise or have the potential to compromise the exercise of professional judgment or obligations, or may be perceived as doing so. It is important to note that a conflict of interest depends on the situation; not on the character or the actions of the individual.

Entities Affected by this Policy

This policy applies to all colleges, departments, units and personnel of the University involved in administering sponsored awards.

Web Address

To be completed by the President's Chief of Staff.

Related Documents

A conflict of interest in research certification form will be administered by the Office of the Provost on an annual basis.

Implementation

- I. Certification of Compliance. On an annual basis, all academic staff members meeting the definition of Investigator as defined in this policy must certify their knowledge of and compliance with this policy by completing a Conflict of Interest Certification form for review by the COIC. **This certification, and all required review of associated disclosures, must occur prior to and within the same fiscal year as the submission of a proposal for funding.** At the time of submission for funding, Investigators must consider the proposed project and update their certification/disclosures as applicable.

To screen for situations that require further review, the Conflict of Interest Certification form requires that academic staff members indicate "yes" or "no" to a series of questions applicable to both themselves and immediate family members. In answering these questions, a Significant Financial Interest (SFI), is a financial interest that is related to an investigator's institutional duties, AND falls into one or more of the following categories:

- a. Remuneration in excess of \$10,000 (\$5,000 for PHS-funded Investigators) from a publicly-traded entity during the last 12 months,
- b. Stock in a publicly traded company valued in excess of \$10,000 (\$5,000 for PHS-funded Investigators) at the time of certification,
- c. A combination of the above two items (stock and income) that exceeds \$10,000 (\$5,000 for PHS-funded Investigators) during the preceding 12 months,
- d. Any amount of equity (stock, stock options, or other ownership interest) in a non-publicly traded entity, including a start-up company,
- e. Remuneration that exceeds \$5,000 from a non-publicly traded entity in the past 12 months, or
- f. Income related to intellectual property rights paid by any source other than the Investigator's current Institution.

The following DO NOT require disclosure:

- g. Salary, royalties, or other remuneration paid to the Investigator from the Institution that currently employs the Investigator,
- h. Income from seminars, lectures, or teaching engagements sponsored by, a federal, state, or local government agency; a U.S. Institution of higher education; or a research institute affiliated with such, a medical center, or an academic teaching hospital,
- i. Income from investments in mutual funds or retirement accounts, as long as the Investigator does not make the investment decisions,
- j. Income for services (e.g., honoraria, advisory committees, and review panels) and travel expenses paid by a federal, state, or local government agency; a U.S. Institution of higher education; or a research institute affiliated with such, a medical center, or an academic teaching hospital, or

Small Business Innovative Research (SBIR) and Small Business Technology Transfer (STTR) Program Phase I awards to small businesses.

k. A disclosure MUST include:

- i. The investigator's current or pending relationship with the outside enterprise or entity in which the academic staff member has a significant financial interest exists;
- ii. The relationship of the research to the enterprise or entity,
- iii. The means by which the investigator proposes to address actual or potential conflicts of interest that arise from his/her (or immediate family members) dual University and enterprise or entity roles, and
- iv. The dollar amount of the financial interest in specified ranges.

Common sense must prevail in the interpretation of these provisions. That is, if a reasonable, disinterested person would question the relationship, it should be disclosed and approval sought for the proposed arrangement. Cases requiring disclosure will report the disclosure using the Certification of Compliance with Policy on Conflict of Interest in Research form administered annually through the Office of the Provost. Those required to sign the Certification/Disclosure are encouraged to provide input with regard to additional factual information, concerns, or any conditions or restrictions that might be imposed by the Institution to manage, reduce, or eliminate such conflict of interest. This information will be made available to the COIC for consideration. Disclosures on file must be updated within 30 days in the case of any new acquisitions or discovery of new significant financial interests.

- II. Management Plans. Examples of conditions or restrictions that might be imposed to manage, reduce, or eliminate actual or potential conflicts of interest can include, but are not limited to:
 - a. Public disclosure of the conflict in publications and presentations
 - b. Disclosure to human subjects participating in the research
 - c. Disclosure to other research team members.
 - d. Appointment of an independent third party to monitor the research
 - e. Modification of the research plan, with approval by the sponsor
 - f. Change of personnel or personnel roles so that the individual in conflict does not participate in the part of the research that could be affected
 - g. Reducing or eliminating the financial interest (e.g., sale of an equity interest)
 - h. Severance of relationships that create financial conflicts
- III. Travel. Disclosure is not required for travel sponsored by or reimbursed by a government agency, a U.S. Institution of higher education or a research institute affiliated with such, a U.S. medical center, or a U.S. academic teaching hospital. However, for PHS-funded Investigators, any reimbursed or sponsored travel paid by a third-party entity, including non-profit organizations, must be disclosed. If on the Roosevelt University Travel

Request Form, it is indicated that an employee's salary is paid from a federal grant or if the individual has a federal grant, the form will be routed to the Division of Research for review. Further disclosure might be required. Travel disclosures must include, at a minimum: the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration. The COIC will determine if further information is required, including a determination or disclosure of monetary value, in order to determine whether the travel constitutes an FCOI with PHS-funded research.

- IV. Disclosure Review Process. All certifications in which a significant financial interest is indicated, their associated disclosures, and any recommended arrangements by or concerns of the signatories will be reviewed by the Roosevelt University's Conflict of Interest Committee, who shall advise the Director of Research and Sponsored Programs.

An actual or potential conflict of interest exists when the Committee reasonably determines that the significant financial interest could directly and significantly affect the design, conduct, or reporting of the research in question. Additional information might be requested by the Committee to make this determination, and the Investigator must comply with this request. If it is determined that a conflict exists, a final written agreement to manage the conflict will be reached by the academic staff member, the Conflict of Interest Committee Chair, Vice Provost of Academic Affairs, Director of Research and Sponsored Programs, the Department Chair, and the Dean and/or Center Director. Departments, Colleges, and Center Directors are responsible for ensuring that required management plans are carried out and monitored until the completion of the research.

Should an academic staff member wish to appeal a decision made by the COIC, he or she may present the appeal in writing to the Committee. The Institutional Official will be made aware of all appeals.

- V. Training. If receiving Public Health Service (PHS) funds, all individuals meeting the definition of Investigator in Section II must take an Institutionally-recognized FCOI training course before utilizing PHS funds and at least once every four years. The Roosevelt University recognizes the FCOI modules 1 and 2 provided through the Collaborative Institutional Training Initiative (CITI), of which ROOSEVELT is a member. Additional training might be required by the Institution more often under certain circumstances (e.g., failure to disclose significant financial interests, noncompliance with approved management plan).

- VI. Responsibilities

- a. Institutional Official (IO). The Roosevelt University Institutional Official, for purposes of this policy, is the Director of Research and Sponsored Programs. The Institutional Official is responsible for the solicitation and review of disclosures of significant financial interests from each Investigator at the Institution. The IO has delegated the solicitation/review responsibility to the Roosevelt University's Conflict of Interest Committee (COIC), with the requirement that IO be kept informed of and is the final signing official for all management plans put in place for significant financial interests determined by the COIC to be a Financial Conflict of Interest.
- b. The Conflict of Interest Committee (COIC). The Roosevelt University's Conflict of Interest Committee consults with the Director of Research and Sponsored Programs. The COIC will be comprised of a minimum of five (5) COIC members, which includes a Chairperson. As necessary, ex-officio members and a non-affiliated member may be included. Members will be chosen to best represent the expertise and interests of the research being conducted at Roosevelt University. COIC members will as necessary to review the disclosures and annual certifications that have been submitted to the Division of Research. The COIC will determine whether an Investigator's submitted SFI could directly and significantly affect the research or is in an entity whose financial interest could be affected by the research. If it is determined that either of these conditions is valid, a Financial Conflict of Interest exists. In the case of a Financial Conflict of Interest and prior to the expenditure of any research funds, the COIC will work with the Investigator, Chair, Dean, and IO to develop a plan to manage or eliminate the conflict, and to ensure to the extent possible that the research is free of bias.

COIC members will serve for a term of three years, at which time membership services and representation of the University's research interests will be reviewed. Members can serve consecutive terms with the concurrence of the IO. The COIC Chair and/or IO reserves the right to replace any committee member for non-performance or reasons related to ethical concerns.

- c. Additional Responsibilities.
 - i. Maintenance of an up-to-date, written, enforced policy on FCOI, made available through a publicly accessible website. This policy is available on the Roosevelt University Policies webpage.
 - ii. Notification to Investigators of new regulations and revised Institutional policy/Investigator responsibilities.
 - iii. Reporting all required information regarding Financial Conflicts of Interest to federal sponsors.

- iv. Making information regarding FCOIs of senior/key personnel on PHS funded projects publicly available.
 - v. Maintenance/retention of all required FCOI records per funding agency requirements.
- d. Academic Staff Member/Investigator.
- i. Being familiar with and abiding by federal regulations and Roosevelt Policy regarding FCOI.
 - ii. Ensuring that FCOI training is complete prior to utilizing PHS funds and at least once every four years, as outlined in section V.
 - iii. Filing an FCOI Certification and disclosure (if appropriate) to the Institution annually and within 30 days of discovering or acquiring a new significant financial interest.
 - iv. Confirming agreement to and complying with any management plan issued by the Institution; retaining documentation that demonstrates compliance with the management plan, such as notices to journal editors or conference audiences, consent forms from human subjects research, and notices to laboratory personnel.
- e. Colleges, Departments, and Center Directors
- i. Colleges, Departments, and Center Directors are responsible for ensuring that academic staff members submit annual certifications and disclosures.
 - ii. Signatories are encouraged to provide input with regard to additional factual information, concerns, or any conditions or restrictions that might be imposed by the Institution to manage, reduce, or eliminate such conflict of interest. Signatories will also be actively involved in the final review of plans to manage or eliminate conflicts.
 - iii. Colleges, Departments, and Center Directors are responsible for ensuring that required management plans are carried out and monitored until the completion of the research.
- f. Awardees and Sub recipients
- i. When the Roosevelt University is the primary awardee of a collaborative PHS- or NSF-funded project, it must assure that the financial interests of all sub recipients are reviewed and eliminated or managed properly.
 - ii. During the proposal stage and during the negotiation of a sub award, all sub recipients/potential sub recipients of PHS funding will be required to certify the following in writing via a Letter of Compliance:

1. The sub recipient Institution has a policy in place to review and manage Significant Financial Conflicts of Interest that meets regulatory requirements.
2. The sub recipient's policy applies to the sub awarded portion of the research project, and
3. The sub recipient must agree that the identification of and management plan of any FCOI identified will be submitted to the awardee Institution for required reporting purposes.
4. If the sub awardee Institution does not have a compliant FCOI program in place, the agreement must indicate that the sub recipient will follow ROOSEVELT FCOI policy, including the pre-award and annual submission of a Certification (and disclosure, if applicable) to the ROOSEVELT COIC within 30 days of the submission of the proposal.

VII. Reporting. The Office of Research and Sponsored Programs is responsible for reporting Financial Conflict of Interest Reports to funding agencies, as applicable:

Public Health Service (PHS)-Funded Projects.

Initial Report. Prior to the expenditure of funds under a PHS-funded research project, the Roosevelt University must report any Investigator Significant Financial Interests that are determined by the COIC, or a sub recipient Institution, to constitute a Financial Conflict of Interest.

Interim Reports. The Institution must submit an FCOI report within sixty (60) days after its determination that an FCOI exists for an Investigator who is newly participating in the project or for an existing Investigator who discloses a new Significant Financial Interest to the Institution during the period of award. A FCOI report is required in cases of noncompliance (when an Investigator does not disclose a previously existing Significant Financial Interest in a timely fashion or the Institution fails to review a previously existing Significant Financial Interest during an ongoing NIH-funded project).

Annual Report. For any Financial Conflict of Interest previously reported by the Institution, the Institution shall provide an annual FCOI report that addresses the status of the financial interest and any changes to the management plan. Annual FCOI reports must specify whether the Financial Conflict of Interest is still being managed or explain why the Financial Conflict of Interest no longer exists. Annual FCOI reports must be submitted to the NIH for the duration of the project period (including extensions with or without funds) at the same time the Institution is required to submit the annual progress report, but through an alternative mechanism.

National Science Foundation (NSF)-Funded Projects

The Roosevelt University must notify NSF's Office of the General Counsel if it determines that it is unable to manage a Conflict of Interest related to an NSF-funded project satisfactorily. If the Roosevelt University determines a financial conflict with NSF research to be unmanageable (i.e. imposing conditions or restrictions would be either ineffective or inequitable, and the potential negative impacts that may arise from a significant financial interest are outweighed by the interests of scientific progress, technology transfer, or the public health and welfare), the NSF Office of the General Counsel will be notified electronically. ROOSEVELT and awardees will cooperate with the OGC's review of the institutional conflict of interest policy, actions taken by the institution with respect to the unmanageable conflict, and NSF requests for confirmation that proposed actions have been accomplished.

- VIII. FCOI Record Retention. The Office of Research and Sponsored Programs is responsible for the maintenance and retention of all financial disclosure documentation and of all actions taken to resolve conflicts of interest for at least three years beyond the date of submission of the final expenditures report of the grant to which they relate, or until the resolution of any funding agency action involving those records, whichever is longer. Additional retention might be required under 45 C.F.R. 74.53(b) and 92.42 (b) for different situations.
- IX. Noncompliance. Failure of any academic staff member to comply with this policy shall constitute grounds for disciplinary action. Disciplinary action is based upon a reasonable investigation of the noncompliance and is consistent with the severity of the violation. A range of examples includes, but is not limited to, the requirement for additional training/monitoring for minor violations up to the imposition of restrictions on an academic staff member's participation in sponsored research for severe or continuing violations.

Additional PHS Requirements. If an investigator fails to disclose a SFI in a timely manner or if for any reason the Institution fails to review a SFI, the Institution must, within 60 days, determine whether the SFI is related to the research, and whether it rises to the level of a FCOI. If found to be an FCOI, a management plan, even if interim, must be implemented. A FCOI report must be made to PHS at this time.

In addition, where it is discovered that Roosevelt University has failed to manage a FCOI or where a researcher has failed to comply with a management plan, the Institution must, within 120 days, complete a retrospective review of research to determine whether the research conducted during the period of noncompliance was biased in the design, conduct, or reporting of the research. If bias is identified, a mitigation report must be developed that outlines a plan of action to eliminate or mitigate the effect of the bias. The results of that determination and the mitigation report must be submitted to PHS.

- X. Public Accessibility. The Institution is required to make its policy on Financial Conflict of Interest publicly accessible via its website. In addition, responses to public information requests for information concerning Significant Financial Conflicts of Interest must be disclosed within five business days in writing. Disclosures can be obtained by contacting coi@Roosevelt.edu and must meet the following criteria:
- a. The significant financial interest was disclosed and is still held by the senior/key personnel as related to the PHS-funded project,
 - b. The Institution determines that the Significant Financial Interest is related to the PHS-funded research, and
 - c. The Institution determines that the Significant Financial Interest is a Financial Conflict of Interest.

The information that must be disclosed includes the following:

- 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 (dollar ranges are permissible: \$0-\$4,999; \$5,000-\$9,999; \$10,000-\$19,999; amounts between \$20,000-\$100,000 by increments of \$20,000; amounts above \$100,000 in increments of \$50,000) or a statement that the interest is one for which the value cannot be readily determined through reference to public prices or other reasonable measures of fair market value.

Online Resources and Forms

It is the policy of Roosevelt University (RU, "the University") that all conflict of interest in research policies and procedures comply with (http://www.nsf.gov/pubs/manuals/gpm05_131/gpm5.jsp#510) .