



**ROLLINS**  
Proposed Policy

<b>Title:</b>	<b>Financial Conflict of Interest Policy for Sponsored Research Projects</b>	<b>Type:</b>	<b>Key Institutional</b>
No: KI 1007			Approval Date: 3-27-2014
Responsible Office: Grants & Contracts, VPAA/Provost			Approved By: P&BC, Pres Staff, & President
Next Review: 2018			Revision No:

### I. Purpose/Introduction/Rationale

*This policy is intended to supplement the existing Rollins College Conflict of Interest policy and applies only to faculty and staff seeking Federal funding for research or education projects.*

The Federal government requires that the College establish and administer a financial conflict of interest and disclosure policy for investigators who conduct research funded by Federal grants. This standard is designed to ensure appropriate management of actual or potential conflicts of interest. The following policy is intended to comply with substantial changes in Public Health Service (PHS) regulations (42 CFR 50 and 45 CFR 94) and to comply with existing conflict of interest policies of the National Science Foundation (NSF). To promote objectivity in research and to foster compliance with Federal regulations, Rollins requires investigators seeking research funding and those who have obtained research funding from PHS, NSF, or other Federal agencies to comply with the following policy on the disclosure of significant financial interests and the management and reporting of financial conflicts of interest.

### II. Definition

**Investigator** is defined as the principal investigator/project director, co-principal investigators/co-project directors, and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research or educational activities funded or proposed for funding by the PHS or NSF.

**Significant financial interest (SFI)** is defined as an interest of monetary value (whether or not the value is readily ascertainable) in one more of the following by the Investigator (including the Investigator's spouse or domestic partner and dependent children) that reasonably appear to be related to the Investigator's institutional responsibilities (teaching, research, and/or service to the College), including the research or educational activities funded or proposed for funding.

- Financial interest in a publicly traded entity if the value of any remuneration received 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. Remuneration includes any salary or other payment for services (e.g., consulting fees, honoraria, paid authorship); equity interest includes stocks, stock options, or other ownership interests, as determined through reference to public prices or other reasonable measures of fair market value.

- Financial interest in a non-publicly traded entity if the value of any remuneration received in the twelve months preceding the disclosure, when aggregated, exceeds \$5,000, or any equity interest holdings in the entity, regardless of dollar value.
- Income from intellectual property rights and interests (e.g., patents, copyrights, and royalties), upon receipt of income related to such rights and interests.
- Reimbursed or sponsored travel, provided that the travel is not 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 affiliated with an institution of higher education. The Investigator must disclose the purpose of the trip, the identity of the sponsor and/or organizer, the destination, duration, and estimated cost of travel.

SFI does not include the following:

- Salary, royalties, or other remuneration paid by the College to the Investigator;
- 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 public or non-profit entities;
- Income from service on advisory committees or review panels for public or non-profit entities;

It should be noted that SFIs, as defined above, do not necessarily mean a financial conflict of interest. All SFIs must be disclosed and reviewed by the College's Institutional Official to determine whether a conflict of interest exists, and determine what conditions or restrictions, if any, should be imposed by the College to manage, reduce, or eliminate such conflict of interest.

**Financial Conflict of Interest (FCOI)** means a SFI that the College's Institutional Official reasonably determines could directly and significantly affect the design, conduct, or reporting of Federally-funded research or educational activities.

**Institutional Official** means the College-designated authority – in this case, the Vice President of Academic Affairs/Provost (VPAA), or his/her designee(s) – who reviews and evaluates all disclosures by Investigators under this policy; determines whether a FCOI exists; develops and implements a management plan for FCOI subject to this policy; performs retrospective review of potential instances of noncompliance with this policy; provides information on Investigator FCOI to the public, as required by agency regulations; reports on College determination of FCOI, implementation of management plans, determination of noncompliance; and the results of any retrospective review, as required by agency regulations; and provides and monitors training of Investigators, as required by agency regulations.

**Public Health Service or PHS** means the Public Health Service of the U.S. Department of Health and Human Services (DHHS), and any components of the PHS to which the authority of the PHS may be delegated. The components of the PHS include, but are not limited to, the National Institutes of Health (NIH) and the Centers for Disease Control (CDC).

**Research** means a systematic investigation, study, or experiment designed to contribute to generalizable knowledge. The term encompasses the following:

- **Basic research** is undertaken primarily to acquire new knowledge without any particular application or use in mind.
- **Applied research** is conducted to gain the knowledge or understanding to meet a specific, recognized need.
- **Development** is the systematic use of the knowledge or understanding gained from research directed toward the production of useful materials, devices, systems, or methods, including the design and development of prototypes and processes.

For the purposes of this policy, **Research** includes as any activity for which funding is available from a PHS or NSF Awarding Component through a grant, contract, or cooperative agreement.

**Funding Agency** or **Agency** means either the PHS of the U.S. DHHS and any components of the PHS to which the authority of the PHS may be delegated, or the NSF and any components of the NSF to which the authority of the NSF may be delegated.

### III. Procedure or Application

#### **A. Procedures for Investigators**

As a condition of applying for and expending funds from the PHS or NSF, each Investigator is responsible for and required to:

1. Disclose all SFIs (and those of the Investigator's spouse/domestic partner and dependent children) related to the Investigator's institutional responsibilities before an Investigator's proposal is submitted to a funding agency. See Appendix A *Significant Financial Interests Disclosure Form*, which must be completed with all supporting documentation and sent to the Institutional Official (see Section III.C. this document) at least 10 days prior to the funding agency's deadline. Supporting documentation that identifies the business enterprise or entity involved and the nature and amount of the interest should be submitted in a sealed envelope marked "confidential" and accompany the disclosure form, for review.
2. Update their disclosures during the period of the award on an annual basis, as determined by the Director of Grants and Contracts.
3. Update their disclosures within 30 days of discovering or acquiring (e.g., through purchase, marriage, or inheritance) any new SFIs.
4. Cooperate in the development of a plan to resolve any FCOI.
5. Comply with any conditions or restrictions imposed by the College to manage, reduce, or eliminate actual or potential conflicts of interests or to forfeit the award.
6. Complete College-provided training on FCOI prior to engaging in research related to any PHS-funded grant or award, and at least every four years (only applies to PHS funding). Training to be offered through the Office of Grants and Contracts.

#### **B. Procedures for Institution**

As a condition of applying for and expending funds from the PHS or NSF, the College is responsible for and required to

1. Maintain an up-to-date, written, enforced FCOI policy that fully complies with PHS and NSF regulations and make the policy publicly accessible via its website. This policy and Disclosure Form will be provided to Investigators along with the College's Grant/Contract Endorsement form, at the time the Investigator informs the Director of Grants and Contracts of his/her plan to submit a proposal to a PHS agency or to NSF.
2. Designate an Institutional Official (see Section III.C. this document) to review disclosures of SFIs of the Investigator and determine whether an Investigator's SFI is related to the proposed agency-funded research, and if it is a FCOI.
3. Develop and implement necessary management plans to manage any identified FCOIs for Investigators, including any sub-awardee Investigators, if applicable.
4. Require each PHS-supported Investigator to complete FCOI training prior to engaging in research related to any PHS-funded grant or award, and at least every four years. Training must be completed immediately (within 30 days) if: (1) the College revises its FCOI policy that affects requirements of Investigators; (2) an Investigator is new to the College; or (3) an Investigator is not in compliance with the policy or management plan. Required FCOI training to be offered through the Office of Grants and Contracts.
5. Send initial, annual, and revised FCOI reports to the funding agency, as required by each agency's regulations, as stated in 42 CFR 50.604(h), 42 CFR 50.605(b), and the NSF Proposal and Award Policies and Procedures Guide (updated annually).
6. If necessary, complete a retrospective review of the Investigator's activities and agency-funded research (with required documentation), and if bias is found with the design, conduct, or reporting of the agency-funded research, provide a Mitigation Report to the agency.
7. Notify the funding agency promptly if an Investigator fails to comply with the College's FCOI policy described herein, or if a FCOI management plan appears to have biased the design, conduct, or reporting of agency-funded research.
8. Make publicly available via its website information concerning identified FCOIs that have been determined to be related to the agency-funded research and are actively held by the Investigator. This information will be made available prior to the expenditure of agency funds and updated annually and within 60 days of any newly identified FCOI. The following information shall be made included:
  - Investigator's name, title, and role with respect to the research project;
  - Name of the entity in which the SFI is held;
  - Nature of the SFI (e.g., equity, consulting fees, travel reimbursement, honoraria, etc.);
  - Approximate dollar range of the SFI or a statement that the interest is one whose value cannot be readily determined through reference to public prices or other reasonable measure of fair market value.

9. Report all identified FCOIs for any sub-recipient Investigators (if applicable) to the funding agency, as required by each agency's regulations.
10. Maintain all FCOI-related records for at least three years after the termination or completion of the award to which they relate.

### **C. Reviewing Disclosures and Managing FCOI**

The Institutional Official (or his/her designee) shall review each SFI disclosure by an Investigator, determine whether the SFI is related to the agency-funded research and whether a FCOI exists, and determine what conditions or restrictions, if any, should be imposed by the institution to manage, reduce, or eliminate the FCOI as part of a formal management plan. A Conflict of Interest exists when the Institutional Official reasonably determines that a SFI could directly and significantly affect the design, conduct, or reporting of the agency-funded research or educational activities. The Institutional Official may request that additional staff or faculty serve on an ad hoc review committee to assist in this review.

Conditions or restrictions that might be imposed to manage, reduce, or eliminate FCOI include, but are not limited to the following:

- public disclosure of SFIs;
- modification of the research plan;
- monitoring of research by independent reviewers;
- disqualification from participation in all or a portion of the funded research that would be affected by SFIs;
- divestiture of SFIs; or
- severance of relationships that create actual or potential conflicts.

*NSF Research Only:* If the Institutional Official determines that imposing the above referenced conditions or restrictions would be ineffective or inequitable, and that the potential negative impacts that may arise from a SFI are outweighed by interests of scientific progress, technology transfer, or the public health and welfare, then the Institutional Official may recommend that, to the extent permitted by agency regulations, the research go forward without imposing such conditions or restrictions. In these cases, the Institutional Official must promptly notify the NSF's Office of General Counsel that the Institution has made this determination.

The Institutional Official shall communicate his/her determination and means for managing, reducing, or eliminating the FCOI to the Investigator, the relevant Principal Investigator or Project Director (if applicable), the appropriate department chair and dean, and the funding agency (as required by agency-specific regulations).

No expenditures on agency awards will be permitted until the Investigator has complied with the disclosure and training requirements of this policy and has agreed, in writing, to comply with any plans determined to be necessary for the management of an FCOI.

All conflicts of interest will be satisfactorily managed, reduced, or eliminated in accordance with agency regulations and any agency-specific reporting regarding the conflict of interest prior to

expenditure of any funds under an award. Agencies will be promptly notified if, at any time, the College finds that it is unable to satisfactorily manage a conflict of interest.

#### **D. Violations of Policy**

Whenever an Investigator has violated this policy or the terms of any management plan required by the Institutional Official (including failure to file or knowingly filing incomplete, erroneous, or misleading disclosure forms) the College will impose sanctions or institute disciplinary proceedings against the violating individual. If the violation results in a collateral proceeding under the College policy regarding research and scholarly misconduct, then the Institutional Official will defer a decision on sanctions until the misconduct inquiry and/or investigation is completed. In addition, the College shall follow agency regulations regarding the notification of the sponsoring agency in the event an investigator has failed to comply with this policy.

#### **E. Record Maintenance**

Records of all FCOI-related documents and of all actions taken to resolve conflicts of interest shall be retained by the Office of the Provost and/or Office of Grants and Contracts for a period of three years after the termination or completion of the award to which they relate.

#### **F. Sub-agreements**

Sub-recipients (including subcontractors and consortium members) from other organizations through which the Institution is carrying out some portion of the proposed research must provide a written certification prior to proposal submission stating that they will either comply with this policy or certify that their organizations are in compliance with Federal regulations regarding FCOI. Prior to the expenditure of funds, Rollins will require a signed written agreement with each sub-recipient with terms that establish whether the FCOI policy of the College or that of the sub-recipient will apply to the sub-recipient's Investigators. The sub-recipient will be required to certify that their FCOI policy complies with the regulations stated herein.

### **IV. Related Policies or Applicable Publications**

Rollins College. (2014). *Rollins College Conflict of Interest Policy*.

Rollins College. (2014). *Faculty Handbook, Research and Scholarly Misconduct Policy*.

### **V. Appendices/Supplemental Materials**

Appendix A: Significant Financial Interest Disclosure Form

### **VI. Rationale for Revision**

Not applicable.

## Appendix A

# Significant Financial Interest Disclosure

(Applicable to all Investigators applying for PHS or NSF funding)

Name \_\_\_\_\_

Department \_\_\_\_\_

Proposal Title \_\_\_\_\_

Proposal Submitted to \_\_\_\_\_

I do not have any significant financial interests\* to disclose at this time.

I am disclosing the following significant financial interests\* (check one) and attaching supporting documentation (in an envelope marked **CONFIDENTIAL**) that identifies the entity involved and the nature and amount of the interest:

\**Significant financial interests* are defined as an interest of monetary value in one more of the following by the Investigator (including the Investigator's spouse or domestic partner and dependent children) that reasonably appear to be related to the Investigator's institutional responsibilities, including the research or educational activities funded or proposed for funding. See full policy on for exempt interests.

Financial interest in a **publicly traded entity** if the value of any remuneration received in the last 12 months and the current value of any equity interest holdings in the entity, when aggregated, exceeds \$5,000. Check all that apply:  
\_\_\_ Salary or other payment for services (e.g., consulting fees, honoraria, paid authorship)  
\_\_\_ Equity interest (e.g., stocks, stock options, or other ownership interests)

Financial interest in a **non-publicly traded entity** if the value of any remuneration received in the last 12 months, when aggregated, exceeds \$5,000; **OR** any equity interest holdings in the entity. Check all that apply:  
\_\_\_ Salary or other payment for services (e.g., consulting fees, honoraria, paid authorship)  
\_\_\_ Equity interest (e.g., stocks, stock options, or other ownership interests)

Income from intellectual property rights and interests (e.g., patents, copyrights, and royalties).

Reimbursed or sponsored travel, provided that the travel is not 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 affiliated with an institution of higher education.

Other significant interests of the Investigator that possibly could affect or be perceived to affect the results of the research or educational activities funded or proposed for funding.

### Further I agree:

- To update this disclosure during the period of the award on an annual basis, or as new reportable significant financial interests are discovered or acquired (within 30 days).
- To cooperate in the development of a plan to resolve any conflicts of interest.
- To comply with any conditions or restrictions imposed by the College to manage, reduce, or eliminate actual or potential conflicts of interests or to forfeit the award.

Investigator: \_\_\_\_\_

Signed

Date