



RESOLUTION-POLICY

X	Action Item
	For Information Only

From: Dr. Eric Milou, Rowan University Senate President
To: Dr. James Newell, Interim Provost
Date: 11/5/12
RE: Senate Resolution 121102-1

**POLICY ON CONFLICT OF INTEREST IN THE DESIGN,
IMPLEMENTATION, OR REPORTING OF
GRANTS AND SPONSORED PROJECTS**

Section 1 – Conflicts of Interest Introduction

1.1 INTRODUCTION

The New Jersey Conflict of Interest Law (N.J.S.A. 52:13D-12, seq.) establishes specific standards of conduct for State employees and officers. This policy supplements State law.

1.2 STATEMENT OF NEED AND PURPOSE

Sponsored projects and grants are vital parts of the Rowan University mission. As these activities grow in sophistication and complexity, they intersect increasingly with industrial explorations and entrepreneurial ventures, creating for investigators the potential for conflicting interests.

Rowan University has developed this policy to protect the integrity of grants and sponsored projects, and to comply with federal regulations. It is the intent and policy of Rowan University as an institution of higher education in receipt of federal and/or other research support to comply with present and future regulations. To that end, this policy is subject to further refinements as other rules are published.

Specifically, the intent of this policy is to identify and eliminate or manage any possible threat to grants and sponsored project objectivity at Rowan University. The main components are disclosure of investigators' financial interests that might be affected by the activity, and application of methods to minimize or eliminate the risks associated with such connections. It is not meant to discourage, but rather to safeguard the pursuit and dissemination of knowledge.

1.3 INSTITUTION RESPONSIBILITIES

Reviews of Conflicts of Interests (COI) will be the responsibility of the Disclosure Review Committee. If a significant financial interest is identified as a conflict or a conflict is reported, then the Committee is charged with assessing whether or not the conflict is tied to the activities of the investigator's field of

expertise or medicine as well as research, teaching, clinical, administrative and purchasing responsibilities.

In the course of reviewing a COI, the Disclosure Review Committee will determine if management plans need to be developed and implemented in order to manage, reduce, or eliminate the COI. Reviewing and approving management plans will be the responsibility of the Disclosure Review Committee.

Disclosure Review Committee, in its institutional responsibilities, may employ and seek review and approval of investigators disclosed conflicts of interest from experts in the investigator's field of expertise or other relevant aspects of the conflicts of interest as it relates to the research and investigator's involvement in the research project.

1.4 DEFINITION and TYPES OF CONFLICT

A conflict of interest exists when it can be reasonably determined that an investigator's personal financial and other concerns could directly and significantly influence the design, implementation, or reporting of grants and sponsored project activities. Faculty and staff of Rowan University have an obligation to scrupulously maintain the objectivity of their grants and sponsored projects, avoiding any conflict of interest.

Conflicts in the design, implementation, or reporting of grants and sponsored projects activities includes but is not limited to financial, commitment, conscience, and institutional conflicts.

Section 2 – General Conflict of Interest

2.1 GENERAL APPLICABILITY

Section 2 of this policy applies to any employee of Rowan University who is responsible for the design, implementation, or reporting of grant and sponsored project activities funded or proposed for funding by any external source. See Section 3 PHS Financial Conflict of Interest for additional requirements related to PHS/PHS operating agency funded or proposed for funding projects and financial conflicts of interest.

Project directors and principal investigators are responsible for ensuring that all participants in a project who are involved with the design, implementation, or reporting of the activity disclose any significant financial interests that would reasonably appear to be affected by the activity. Individuals, who come to work on an established project through reallocation of effort, hiring, transfer, promotion, etc., and thereby take on a responsible position in a project, must also disclose any such significant financial interests. Investigator includes the investigator's immediate family, which is defined as his/her spouse or domestic partner and dependent children.

Collaborators, subcontractors, subrecipients, and visiting scientists must either comply with this policy or provide a certification to the Office of Research and Sponsored Programs that their institutions are in compliance with pertinent federal policies and that they in turn are in compliance with their own institutional policies.

2.2 GENERAL SIGNIFICANT FINANCIAL INTEREST and CONSULTING PRINCIPLES

Any Rowan University employee responsible for the design, implementation, or reporting of grants and sponsored project activities funded or proposed for funding by external sources must reveal all

current significant financial interests that would reasonably appear to be affected by the activity. This section of the policy is not applicable to PHS/PHS operating agency funded or proposed for funding projects (see Section 3 – PHS Financial Conflict of Interest).

Significant financial interest (SFI) is defined as any current financial interest of the investigator and his/her immediate family that could reasonably appear to be affected by the activities proposed for funding; or any interest held by the investigator and his/her immediate family in a business entity (company, corporation, or other enterprise) whose financial interest might reasonably appear to be affected by such activities.

Specifically, SFI's might include, but are not limited to, any of the following:

- Anything of significant monetary value, including salary or other payments for services, such as consulting fees or honoraria;
- Direct equity interests, such as stock, stock options, or ownership interests;
- Intellectual property rights owned by the investigator, such as patents, copyrights, and royalties from such rights.

The term does not include:

- Financial interests in business enterprises or entities that, when aggregated for the investigator and his/her immediate family, meet both of the following tests:

- i) the financial interest does not exceed \$10,000 in value as determined through reference to public prices or other reasonable measures of fair market value, and
- ii) the financial interest does not represent more than a five percent ownership interest in any single entity;

- Salary, royalties, or other remuneration from Rowan University;
- Salary, royalties, or other payments that, when aggregated for the investigator and his/her immediate family, are not expected to exceed \$10,000 during the next twelve month period;
- Income from seminars, lectures, consulting assignments 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.

An investigator may choose to disclose any other financial or related interest that might present an actual, potential, or perceived conflict of interest. Disclosure can be a key factor in protecting an individual's reputation and career from potentially harmful allegations of misconduct.

Consulting Principles

There are many reasons why faculty members should engage in outside consulting work. It is desirable that they remain in close communication with the world outside the institution and especially with that part of the world concerned with their area of specialization. Consulting is a

means of maintaining this liaison as well as of offering solutions to practical problems and thereby testing the soundness of theories taught in the classroom and laboratories. While consulting activities often enhance a faculty member's value to Rowan University, they can result in conflicts of interest and conflicts of commitment which compromise the faculty and the institution.

In private consulting, it must be kept clear that the faculty member does not represent the University. Private consulting activities of faculty members must be viewed in relation to their overall responsibilities to Rowan University and should not become so extensive that they interfere with those responsibilities.

2.3 GENERAL REVIEW OF DISCLOSURES

A Disclosure Review Committee (DRC) will review all disclosure statements. The committee will be co-chaired by the Associate Provost for Research. The president will appoint three additional faculty members representing the diverse colleges, departments, and programs at Rowan University. Members will serve three year staggered terms.

The committee will be responsible for determining whether the significant financial interests of the investigator could reasonably be expected to affect the design, schedule, implementation, or reporting of the activities funded or proposed for funding in sponsored projects. The committee may request additional clarifying information, as well as a management plan for the conflict, from the investigator which will be treated as non-public information to the extent allowed by law. Upon completion of its review, the committee will advise the president of the University of its findings and may recommend implementation of a management plan to reduce, mitigate, or eliminate the proposed conflict.

2.4 GENERAL MANAGEMENT PLANS FOR CONFLICT

The committee will review the proposed conflict management plan, add conditions and/or restrictions, and approve it to ensure that any conflict is reduced, eliminated, or managed. Such conditions or restrictions may include, but are not limited to, the following:

- Public disclosure of significant financial interests;
- Monitoring of the research by independent reviewers;
- Modification of the planned activities (possibly subject to sponsor approval);
- Disqualification from participation in all or part of the project;
- Divestiture of significant financial interests;
- Severance of relationships creating conflict.

In all cases, resolution of the conflict or establishment of an acceptable conflict management plan must be achieved and approved by the president before expenditure of any funds under an award.

Section 3 – PHS Financial Conflict of Interest

3.1 STATEMENT OF NEED AND PURPOSE and APPLICABILITY

Public Health Services has revised the existing Financial Conflict of Interest Regulation, Promoting Objectivity in Research (42 CFR Part 50 Subpart F and 45 CFR Part 94). As a result of the revised regulations, institution's receiving Public Health Service (PHS) funds from the National Institutes of Health (NIH) and other PHS operating agencies must be able to demonstrate greater transparency and accountability regarding financial conflict of interest management and reporting.

Section 3 of this policy applies to grants and sponsored projects funded or proposed for funding by PHS or a PHS funded/operating agency, including but not limited to NIH, and whose purpose of the project(s) is research.

Research is defined as the following:

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

Project Directors, Principal Investigators and Senior/Key Personnel

Project Directors, Principal Investigators and Senior/Key personnel requesting and receiving PHS/PHS operating agency funding are expected to adhere and conform to the requirements as set forth in Section 3 – PHS Financial Conflict of Interest. Other Key personnel who are involved with the design, implementation, or reporting of the sponsored research is also subject to the requirements in this Section 3. Investigator means the project director or principal Investigator and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research funded by the PHS, or proposed for such funding, which may include, for example, collaborators or consultants. Investigator's spouse or domestic partner and dependent children must be considered when investigators are reviewing significant financial interests. Any significant financial interest owned/ or held in the names of the investigator's spouse or domestic partner and dependents must be reported if the significant financial interest meets the criteria as stated in Section 3.3 PHS Significant Financial Interests.

Sub-recipients

Sub recipients on PHS/PHS operating agencies funded or proposed for funding projects are subject to comply and follow the regulations as set forth in Financial Conflict of Interest Regulation, Promoting Objectivity in Research (42 CFR Part 50 Subpart F and 45 CFR Part 94), even though the sub recipients are not directly awarded the funds from PHS or any related PHS operating agency. Sub recipients must demonstrate or provide adequate assurances that their institution policies and procedures are in compliance with the regulation, and are subject to requests to provide or complete a significant financial interest form upon request.

Examples of Public Health Services (PHS) Operating Agencies:

Administration for Children and Families (ACF)

Administration on Children, Youth and Families (ACYF)
Administration for Community Living (ACL)
Agency for Healthcare Research and Quality (AHRQ)
Agency for Toxic Substances and Disease Registry (ATSDR)
Centers for Disease Control and Prevention (CDC)
Centers for Medicare & Medicaid Services
Food and Drug Administration (FDA)
Health Resources and Services Administration (HRSA)
Indian Health Services (IHS)
National Institutes of Health (NIH)
National Cancer Institute (NCI)
Substance Abuse and Mental Health Services Administration (SAMHSA)

3.2 INSTITUTION RESPONSIBILITIES

Pertaining to 2011 Revised PHS Regulations related to COI's, any institution seeking PHS/PHS operating agency funded research needs to review Significant Financial Interest's to determine if a Financial Conflict of Interest (FCOI) exists or does not exist. This section expands upon Section 1.3 Institution Responsibilities; see Section 1.3 for additional policy requirements.

3.3 PHS SIGNIFICANT FINANCIAL INTERESTS

See section 2.2 General Significant Financial Interest and Consulting Principles for a definition of significant financial interest. For PHS/PHS operating agency funding or proposed for funding, the threshold for significant financial interests is \$5,000. See below for further details.

Significant Financial Interests include, but are not limited to, any of the following:

- For publicly traded entities:
 - If the value of any remuneration received from the entity in the 12 months preceding the disclosure, when aggregated, exceeds \$5,000. Remuneration includes salary, and any payment for services not otherwise identified as salary – examples include, but are not limited to, consulting fees, honoraria, paid authorship, etc.
 - If the value of any equity interest as of the date of disclosure, when aggregated, exceeds \$5,000. Equity includes any stock option, or other ownership interest, as determined through reference to public prices or other reasonable measure of fair market value.
- For non-publicly traded entities:
 - If the value of any remuneration received from the entity in the 12 months preceding the disclosure, when aggregated, exceeds \$5,000.
 - If any equity interest as of the date of disclosure is held. Equity includes any stock option or other ownership interest.
- Intellectual property rights and interests – for example, patents, copyrights – upon receipt of income related to such rights and interests.

Significant Financial Interests do not include:

- Salary, royalties or other remuneration paid by the institution, if the investigator(s) are currently employed or otherwise appointed by the institution
- Intellectual property rights assigned to the institution and agreements to share in royalties related to such rights
- Income from investment vehicles, such as but not limited to mutual funds, retirement accounts, provided the investigator(s) do not have direct control of investment decisions in such investment vehicles
- Income from seminars, lectures, or teaching engagements sponsored by a federal, state, or local government agency, an Institution of higher education as defined in 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, or 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.

3.4 DISCLOSURES

Investigators identified in the grant and sponsored project which are funded or proposed to be funded by PHS/PHS operating agency need to disclose all Significant Financial Interests (SFIs) that are related to the investigator's institutional responsibilities and expertise and meet regulatory thresholds. All disclosures and relevant information obtained during the disclosure process and afterwards, is considered confidential information, retained in the strictest of confidence, and is subject to rules and regulations as they apply.

Travel

Investigators must disclose the occurrence of any reimbursed or sponsored travel, which is paid on behalf of the investigator and not reimbursed to them so the exact monetary value is / may not be readily available, and the travel is related to their institutional responsibilities. Rowan University, in its institutional responsibilities, may inquire and request additional information related to travel disclosed by the investigator on disclosure forms.

Travel does not include travel reimbursed or sponsored by a:

- Federal, state or local government agency
- Institution of higher education
- Academic teaching hospital
- Medical center
- Research institute that is affiliated with an institution of higher education

Consulting Agreements and Engagements

Special attention must be paid to consulting agreements and engagements. If the consultation appears to be related to investigators' institutional responsibilities, then that consulting agreement and engagement must be disclosed on disclosure forms regardless of monetary value or aggregated value of remuneration received in the preceding 12 month period or as of the date of disclosure.

Disclosure form(s) needs to be completed and provided to the Office of Sponsored Programs during the following times:

- Prior to the submission of the application to PHS/PHS operating agency
- Annually, during the period of the award. Annual progress reports require Financial Conflicts of Interest to be disclosed
- Within 30 days of discovering or acquiring a new *Significant Financial Interest* as defined above – examples include but not limited to, purchase, marriage, inheritance, etc.
- For any new Investigator assigned to or joining the research project during either the pre-award or post-award stage of the project

Disclosure Review Committee, in the course of its duties and responsibilities, can identify a significant financial interest (SFI) if not reported by an investigator. If an SFI is identified by the Disclosure Review Committee, then the Disclosure Review Committee will conduct a review and determine if a Financial Conflict of Interest (FCOI) exists or does not exist. If the SFI is determined to be a financial conflict of interest, then a retrospective review of the project must occur to determine if bias exists or does not exist in the research. The Disclosure Review Committee, in its institutional responsibilities, may require and employ the assistance of experts in the field of research administration, experts in the field of study, and/or other consultants that are applicable to the nature of the financial conflict of interest and the research purpose and type.

3.5 REVIEW OF DISCLOSURES

This section expands upon Section 2.2 General Review of Disclosures; see Section 2.2 for additional policy requirements. When the Disclosure Review Committee determines that the objectivity of research may be compromised due to a SFI that is deemed an FCOI, then the Disclosure Review Committee is responsible for determining whether or not a Management Plan needs to be developed and implemented.

3.6 MANAGEMENT PLANS FOR CONFLICT

This section expands upon Section 2.3 General Management Plans for Conflict; see Section 2.3 for additional policy requirements. If an FCOI exists, the Disclosure Review Committee is responsible for determining whether or not a Management Plan is required and the creation of a Management Plan. The investigator with the conflict of interest is allowed to participate and provide recommendations related to the Management Plan. After creation of the proposed Management Plan, the Disclosure Review Committee will be responsible for determining the effectiveness of the plan and implementing the plan. In the committee's attempts to implement and develop a sound Management Plan, the committee can add conditions or restrictions to ensure that any conflict is reduced, eliminated, or managed.

In all cases, resolution of the conflict or establishment of an acceptable Management Plan must be achieved and approved by the President of Rowan University before expenditure of any funds under an award.

If at any time it is determined that there is bias in research, investigator fails to comply with Management Plan, or Management Plan is determined to have biased the design, conduct, or reporting of the PHS/PHS operating agency funded research, then the Disclosure Review Committee must notify PHS/PHS funding agency promptly (within 5 to 10 business days of determination).

3.7 RETROSPECTIVE REVIEW

If a Financial Conflict of Interest (FCOI) is not identified or managed in a timely manner, Rowan University will conduct and complete a review of the investigator(s) pre-award and post-award activities and the current project's progress and status to determine bias in the design, conduct or reporting of such research within 120 days when Rowan University determines noncompliance with Rowan's Conflict of Interest policy, the regulation, or other circumstance that resulted in nondisclosure of an SFI or noncompliance with policy and regulation. Examples of noncompliance include, but are not limited to:

- Investigator(s) do not disclose a Significant Financial Interest (SFI)
- SFI was previously reviewed and at that time was not identified as an FCOI
- The Institution does not review or manage an FCOI
- Investigator fails to comply with the Management Plan
- Management Plan is determined to have biased the design, conduct, or reporting of the PHS/PHS operating agency funded research

The retrospective review may encompass a review of investigator travel and any publications authored by the investigator during the retrospective review. In addition, the Disclosure Review Committee retains the right to conduct interviews, monitor research work and related meetings involving the research, or appoint a representative to conduct a peer review and/or independent review of the research conducted to date.

If bias is found to occur during the course of the Retrospective review, then the Mitigation Report needs to document the description of the impact of the bias on the research project and the institution's plan of action or actions taken to eliminate or mitigate the effect of the bias, including some statements such as 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. Upon completion and approval of the Mitigation Report, the report needs to be submitted to PHS/PHS operating agency. Furthermore, if PHS/PHS operating agency determines that a 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 the institution as required by the regulation, the institution shall require the investigator to do the following:

- Disclose the FCOI in each public presentation of the results of the research
- Request an addendum to previously published presentations

Mitigation reporting can be conducted by the Disclosure Review Committee, personnel appointed by the Disclosure Review Committee or an independent reviewer. The final mitigation report must be reviewed and agreed upon by the Disclosure Review Committee.

3.8 FINANCIAL CONFLICT OF INTEREST (FCOI) REPORTING

When Financial Conflicts of Interest (FCOI) exists, then reporting of the FCOI must be performed timely and sent to PHS/PHS operating agency. Mandatory reporting of FCOI's and related documents may encompass any one of, or including all of the following aspects of the FCOI policy:

- Financial Conflict of Interest, in existence
- Management Plan development
- Mitigation Report creation
- Noncompliance with Conflict of Interest Policy

Expenditure of any funds under an award that has an investigator(s) with an FCOI(s) will not occur until the FCOI(s) are reported to PHS/PHS operating agency.

3.9 PUBLIC DISCLOSURE OF FINANCIAL CONFLICTS OF INTEREST

Public requests to review Financial Conflicts of Interest (FCOI) must be made in writing and include at a minimum the following information:

- Name and address of the person requesting the information, including the address of where to send the information
- Name of Investigator(s) whose FCOI information is requested

If the above information is not provided in writing, then Rowan University will make an attempt(s) to obtain that information in order to process the request. Furthermore, all public requests must be directed to the Office of Sponsored Programs (OSP).

Significant Financial Interests (SFI) of the investigator that meets all the criteria below are reportable to the public:

- The Significant Financial Interest was disclosed and is still held by the senior/key personnel. Senior/key personnel are the PD/PI and any other person identified as senior key personnel in the subaward or application to the PHS/PHS operating agency, progress report or any other report submitted to the PHS/PHS operating agency;
- The Disclosure Review Committee determines the SFI is related to the PHS/PHS operating agency funded research; and
- The Disclosure Review Committee determines the SFI is a **Financial Conflict of Interest (FCOI)**.

OSP must provide the requested information within 5 business days of receiving a public request starting on the day when OSP is in receipt of all of the required information from the public. Investigator(s) relationships that need to be made public are only FCOI's that are disclosed and continue to be held. Office of Sponsored Programs is responsible for responding to public requests.

3.10 INVESTIGATOR TRAINING

Rowan University will use an online, web-based module to administer training related to the 2011 PHS revised Financial Conflict of Interest (FCOI) regulation.

Training on FCOI is mandatory for all investigators who will propose for funding or are funded by PHS/PHS operating agencies. Training is required under the following circumstances:

- Prior to engaging in covered research (PHS/PHS operating agency)
- Every 4 years

Even if the investigator has already completed training, training is mandatory for the investigator if any of the following occurs:

- Revisions to Conflict of Interest policy related to Section 3 – PHS Financial Conflict of Interest
- Revisions and associated changes in the regulation
- Revisions to procedures associated with FCOI policy, only if the revised procedures affects requirements of investigators

- Investigator(s) are not in compliance with Rowan University's FCOI policy or approved Management Plan(s)

In Rowan University's attempt to conform to 2011 revised PHS regulations and fulfill its institutional responsibilities, investigators required to complete FCOI training that have not completed FCOI training or provided satisfactory evidence that FCOI training has been completed, will result in the delay of expenditure of any funds under an award.

Section 4 – APPEALS, ENFORCEMENT, AND RECORD RETENTION

4.1 APPEALS

Appeal of the committee's decision may be made to the President of Rowan University. After the President or representative of the President has made a final decision, the committee will inform the Investigator.

4.2 COMPLIANCE

As part of the Disclosure Statement, each investigator must certify that, if the Disclosure Review Committee determines a conflict exists, the investigator will adhere to all conditions or restrictions imposed upon the project and will cooperate fully with the individual(s) assigned to monitor compliance.

4.3 ENFORCEMENT

Failure to properly disclose relevant financial and other interests or to adhere to conditions or restrictions imposed by the Disclosure Review Committee will be considered a deviation from accepted standards of conducting activity at Rowan University, which may be subject to appropriate enforcement actions as prescribed by Rowan University policy, faculty handbook, and employee contracts.

4.4 RECORD RETENTION

Office of Sponsored Programs and the Grants Accounting Offices will maintain records of all disclosures and associated activities securely and confidentially.

All records will be maintained for at a minimum of seven (7) years from the end date of an award or three (3) years after resolution of any government action involving the records, whichever is latter. In some situations, records will be maintained in accordance with Title 45 – Public Welfare Act – Subchapter A: General Administration: Subparts and Sections 74.53 (b) and 92.42 (b).

4.5 FEDERAL REGULATIONS REFERENCES

Department of Health and Human Services. Responsibility of Applicants for Promoting Objectivity in Research for Which PHS Funding is Sought. July 11, 1995. 60 Fr 35810, Part III. CFR Part 45 – Public Welfare Act. Subtitle A – DHHS. Subchapter – General Administrative Requirements. Parts 74 and 92.

National Science Foundation. Investigator Financial Disclosure Policy. July II, 1995.

60 FR 35810, Part III

For additional information, contact: Associate Provost for Research (856) 256-4057

Acceptance:

_____ I give my approval. I have forwarded this item to _____ for implementation.

_____ No approval is actually needed. I have forwarded this item to the following individual or office for informational purposes only:

ADDITIONAL REVIEW NEEDED:

_____ I am willing to give approval if the following modification(s) are made:

_____ Before I can approve or reject this item, I need clarification on the following:

_____ I have forwarded this item to the following individual or office for further consideration and consultation.

Rejection:

_____ I decline acceptance of this item for the following reason:

Please Return this Copy to the University Senate President ~ Retain a Copy for Your Records