Conflict of Interest in the Design, Implementation, or Reporting of Grants and Sponsored Projects

ROWAN UNIVERSITY POLICY

TITLE: Policy on Conflict Of Interest in the Design, Implementation, or Reporting of Grants and Sponsored Projects

SUBJECT: Research

POLICY NO: RES. 2015: 01

APPLIES: University-Wide

ISSUING AUTHORITY: President

RESPONSIBLE OFFICER: Vice President of Research

ADOPTED: 10-07-2015

LAST REVISION: 11/09/2015

I. PURPOSE

The purpose of this policy is to protect the integrity of grants and sponsored projects, and to comply with federal regulations.

II. ACCOUNTABILITY

Under the direction of the President, the Vice President for Research shall implement and ensure compliance with this policy.

III. APPLICABILITY

This policy applies to all faculty, employees, students, collaborators, subcontractors, sub-recipients, and visiting scientists 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. This also includes the principle investigator’s immediate family, which is defined as his/her spouse or domestic partner and dependent children.

IV. DEFINITIONS

1. *Investigator:* Principal Investigator, co-principal investigator, co-investigators and any other University personnel (including faculty, non-faculty employees, residents, postdoctoral trainees and students) who, in the course of their association with the University are or will be responsible for the design, conduct, administration, collaboration, analysis and/or reporting of either research or training activities, funded or proposed for funding by any sponsor, or of unsponsored research or training activities.

2. *Research:* 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.

3. *Significant financial interest (SFI):* 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. Immediate family is defined as his/her spouse or domestic partner and dependent children.

4. **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.

V. REFERENCES

1. 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.
4. For additional information, contact: Vice President for Research (856) 256-4057

VI. POLICY

1. 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.
2. 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.
3. 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.
4. Institution Responsibilities
   a. Reviews of Conflicts of Interests (COI) will be the responsibility of the Conflict of Interest Committee (COIC), as delegated by the Rowan University Vice President for Research or Rowan-SOM Vice Dean for Research. 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.
   b. In the course of reviewing a COI, COIC 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 Rowan University Vice President for Research or Rowan-SOM Vice Dean for Research or other senior administrators of Rowan University.
5. Definition and Types of Conflict
   a. 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.
   b. 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.
6. Procedure
Procedures should be followed according to Managing Conflict of Interest Policy. This policy for investigator conflict of interest should be followed in place of any procedure indicated in this policy.

VII. GENERAL CONFLICT OF INTEREST

1. General Applicability
   a. This section 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.
   b. 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.
   c. Collaborators, subcontractors, sub-recipients, 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. General Significant Financial Interest and Consulting Principles
   a. 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 Attachment 1 Section 5 – Financial Conflict of Interest).
   b. Attachment 1 contains what SFI’s might include and do not include.
   c. 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.
   d. Consulting Principles
      i. 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.
      ii. 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.

3. General Review of Disclosures
   a. A Conflict of Interest Committee (COIC) will review all disclosure statements. The committee will be co-chaired by the Rowan University Vice President for Research and Rowan-SOM Vice Dean 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.
   b. 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 finding and may recommend implementation of a management plan to reduce, mitigate, or eliminate the proposed conflict.

4. General Management Plans For Conflict
   a. 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:
      i. public disclosure of significant financial interests;
      ii. monitoring of the research by independent reviewers;
      iii. modification of the planned activities (possibly subject to sponsor approval);
      iv. disqualification from participation in all or part of the project;
      v. divestiture of significant financial interests and
      vi. severance of relationships creating conflict.
   b. In all cases, resolution of the conflict or establishment of an acceptable conflict management plan must be achieved and approved by the Vice President of Research before expenditure of any funds under an award.

VIII. PHS FINANCIAL CONFLICT OF INTEREST

1. Statement Of Need And Purpose and Applicability
   a. 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.
   b. This section applies to grants and sponsored projects funded or proposed for funding by PHS or a PHS funded/operating agency, including but not limited to National Institutes of Health (NIH), and whose purpose of the project(s) is research.
   c. Attachment 2 contains examples of Public Health Services (PHS) Operating Agencies.

2. Institution's 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. PHS Significant Financial Interests
   a. See section VI.B.2 under 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.
   b. Significant Financial Interests include, but are not limited to, any of the following:
      i. For publicly traded entities:
         1. 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.
         2. 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.
      ii. For non-publicly traded entities:
         1. If the value of any remuneration received from the entity in the 12 months preceding the disclosure, when aggregated, exceeds $5,000.
         2. If any equity interest as of the date of disclosure is held. Equity includes any stock option or other ownership interest
      iii. 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

i. Salary, royalties or other remuneration paid by the institution, if the investigator(s) are currently employed or otherwise appointed by the institution

ii. Intellectual property rights assigned to the institution and agreements to share in royalties related to such rights

iii. 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

iv. 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.

v. 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.

4. Disclosures

a. 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 (Attachment 3). 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.

b. Travel

i. 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.

ii. Travel does not include travel reimbursed or sponsored by a:

1. federal, state or local government agency;
2. institution of higher education;
3. academic teaching hospital;
4. medical center
5. research institute that is affiliated with an institution of higher education

iii. Consulting Agreements and Engagement

1. 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.

2. Disclosure form(s) needs to be completed and provided to the Office of Sponsored Programs, Office of Research, and RowanSOM – Research and Sponsored Program Office during the following times:

   a. prior to the submission of the application to PHS/PHS operating agency;
   b. annually, during the period of the award. Annual progress reports require Financial Conflicts of Interest to be disclosed
   c. 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.
   d. for any new Investigator assigned to or joining the research project during either the pre-award or post-award stage of the project.

3. COIC, 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 COIC, then the COIC 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 COIC, 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.

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 COIC determines that the objectivity of research may be compromised due to a SFI that is deemed an FCOI, then the COIC, as delegated by the Rowan University Vice President for Research or Rowan-SOM Vice Dean Research, is responsible for determining whether or not a Management Plan needs to be developed and implemented.

6. Management Plans For Conflict
   a. 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 COIC, as delegated by the Rowan University Vice President for Research or Rowan-SOM Vice Dean Research, 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. 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.
   b. 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 or an appointee of the President of the University before expenditure of any funds under an award.
   c. 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 PHS/PHS funding agency must be notified promptly (within 5 to 10 business days of determination).

7. Retrospective Review
   a. 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:
      i. investigator(s) do not disclose a Significant Financial Interest (SFI);
      ii. SFI was previously reviewed and at that time was not identified as an FCOI;
      iii. the Institution does not review or manage an FCOI;
      iv. investigator fails to comply with the Management Plan
      v. management Plan is determined to have biased the design, conduct, or reporting of the PHS/PHS operating agency funded research
   b. The retrospective review may encompass a review of investigator travel and any publications authored by the investigator during the retrospective review. In addition, the COIC, as delegated by the Rowan University Vice President for Research or Rowan-SOM Vice Dean for Research, 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.
   c. 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 may require the investigator to do the following:
   i. Disclose the FCOI in each public presentation of the results of the research
   ii. Request an addendum to previously published presentation

8. Financial Conflict of Interest (FCOI) Reporting
   a. When Financial Conflicts of Interest (FCOI) exists, then reporting of the FCOI must be performed timely and sent to the 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:
      i. financial Conflict of Interest, in existence;
      ii. management Plan development;
      iii. mitigation Report creation an
      iv. noncompliance with Conflict of Interest Policy
   b. Expenditure of any funds under an award that has an investigator(s) with an FCOI(s) will not occur until the FCOI(s) is/are reported to PHS/PHS operating agency.

   a. Public requests to review Financial Conflicts of Interest (FCOI) must be made in writing and include at a minimum the following information:
      i. name and address of the person requesting the information, including the address of where to send the information
      ii. name of Investigator(s) whose FCOI information is requested
   b. 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), Office of Research, or Rowan-SOM Research and Sponsored Programs Office.
   c. Significant Financial Interests (SFI) of the investigator that meets all the criteria below are reportable to the public:
      i. the Significant Financial Interest was disclosed and is still held by the investigator Any other person identified and named in the subaward or application to the PHS/PHS operating agency, progress report or any other report submitted to the PHS/PHS operating agency;
      ii. the COIC determines the SFI is related to the PHS/PHS operating agency funded research;
      iii. the COIC determines the SFI is a Financial Conflict of Interest (FCOI).
   d. Office of Sponsored Programs (OSP), Office of Research, or Rowan-SOM Research and Sponsored Programs Office must provide the requested information within 5 business days of receiving a public request starting on the day when the above offices are/is in receipt of all of the required information from the public. Investigator(s), and any other person identified and named in the sponsored or unsponsored project, relationships that need to be made public are only FCOI's that are disclosed and continue to be held. Office of Sponsored Programs (OSP), Office of Research, or Rowan-SOM Research and Sponsored Programs Office is responsible for responding to public requests.

10. Investigator Training
    a. Rowan University will use an online, web-based module to administer training related to the 2011 PHS revised Financial Conflict of Interest (FCOI) regulation.
    b. 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:
       i. prior to engaging in covered research (PHS/PHS operating agency)
       ii. every 4 years
    c. Even if the investigator has already completed training, training is mandatory for the investigator if any of the following occurs:
       i. revisions to Conflict of Interest policy related to Attachment 1 Section 5 – Financial Conflict of Interest
       ii. revisions and associated changes in the regulation
       iii. revisions to Procedures for Investigator Conflict of Interest
       iv. investigator(s) are not in compliance with Rowan University's FCOI policy or approved Management Plan(s)
d. 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. Failure to do so will result in the delay of expenditure of any funds under an award.

IX. APPEALS, ENFORCEMENT, AND RECORD RETENTION

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.

2. Compliance
   As part of the Disclosure Statement, each investigator must certify that, if the COIC 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.

3. Enforcement
   Failure to properly disclose relevant financial and other interests or to adhere to conditions or restrictions imposed by the COIC 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. Record Retention
   a. Office of Sponsored Programs (OSP), Office of Research, or Rowan-SOM Research and Sponsored Programs Office will maintain records of all disclosures and associated activities securely and confidentially.
   b. All records will be maintained for at least 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 later. 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).

X. ATTACHMENTS

1. Attachment 1 - Significant Financial Interests
2. Attachment 2 - Public Health Services (PHS) Operating Agencies
3. Attachment 3 - Significant Financial Interest Disclosure Form

ATTACHMENT 1
SIGNIFICANT FINANCIAL INTEREST (SFI)

Specifically, significant financial interest (SFI) might include, but are not limited to, any of the following:

1. anything of significant monetary value, including salary or other payments for services, such as consulting fees or honoraria;
2. direct equity interests, such as stock, stock options, or ownership interests and
3. intellectual property rights owned by the investigator, such as patents, copyrights, and royalties from such rights.

The term does not include:

1. Financial interests in business enterprises or entities that, when aggregated for the investigator and his /her immediate family, meet both of the following tests:
   a. the financial interest does not exceed $5,000 in value as determined through reference to public prices or other reasonable measures of fair market value,
   b. the financial interest does not represent more than a five percent ownership interest in any single entity;
2. Salary, royalties, or other remuneration from Rowan University;
3. Salary, royalties, or other payments that, when aggregated for the investigator and his/her immediate family, are not expected to exceed $5,000 during the next twelve month period;
4. Income from seminars, lectures, consulting assignments 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.
5. Income from service on advisory committees or review panels for 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.

ATTACHMENT 2
PUBLIC HEALTH SERVICES (PHS) OPERATING AGENCIES

Examples of Public Health Services (PHS) Operating Agencies:

1. Administration for Children and Families (ACF)
2. Administration on Children, Youth and Families (ACYF)
3. Administration for Community Living (ACL)
4. Agency for Healthcare Research and Quality (AHRQ)
5. Agency for Toxic Substances and Disease Registry (ATSDR)
6. Centers for Disease Control and Prevention (CDC)
7. Centers for Medicare & Medicaid Services
8. Food and Drug Administration (FDA)
9. Health Resources and Services Administration (HRSA)
10. Indian Health Services (IHS)
11. National Institutes of Health (NIH)
12. National Cancer Institute (NCI)
13. Substance Abuse and Mental Health Services Administration (SAMHSA)

ATTACHMENT 3
SIGNIFICANT FINANCIAL INTEREST DISCLOSURE FORM
Significant Financial Disclosure Form

INVESTIGATOR FINANCIAL & OTHER PERSONAL INTERESTS DISCLOSURE FORM - Part 1

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TYPE

- Research
- Training/Education
- Service
- Other

NOTHING TO DISCLOSE: CHECK "NO" COLUMN BELOW

I, and/or my spouse, domestic partner, children, parents, and siblings who reside in the same household do not have, within the previous twelve (12) months, any financial or other personal interests (as defined on the next page of this document) to disclose.

DISCLOSURE TO BE MADE: CHECK "YES" COLUMN BELOW

I, and/or my spouse, domestic partner, children, parents, and siblings who reside in the same household DO/DOES have, within the previous twelve (12) months, financial or other personal interests (as defined on the next page of this document) to disclose.

I certify that the information on this form is correct; that I have read and understood the Rowan University Conflict of Interest Policy; that, to the best of my knowledge, all required disclosures of financial and other personal interests have been made herein; that I will complete a Disclosure Form on an annual basis during the duration of the research or more frequently as new interests are obtained or if my situation with respect to potential conflict of interest otherwise changes since my original disclosure, and submit it to the Office of Sponsored Programs and Office of Research that I will comply with any conditions or restrictions imposed by Rowan University to manage, reduce or eliminate conflicts of interest.

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NOTE: If you have indicated Yes above, then please provide a brief description of how the financial or other personal interest relates to the research and investigator's institutional responsibilities.

- This project involves a contract, subcontract or collaboration with an outside institution or group.

- Attached is a written assurance from an appropriate official of this outside entity that individuals from the outside entity who will participate in this project comply with the outside entity's investigator conflict-of-interest policy and that such policy meets the requirements of the PHS (42 CFR Part 50, Subpart F).

- In the event the outside entity has no investigator conflict-of-interest policy, attached are a written assurance from an appropriate official of this outside entity that individuals from the outside entity who will participate in this project comply with Rowan University’s Conflict of Interest policy, plus all Rowan University Disclosure Forms completed by these individuals.

Signature of Department Chair (or Dean / Investigator Chair) of Subdepartment

Date

Signature of Department Chair (if project involves more than one department)

Date

Signature of Department Chair (if project involves more than one department)

Date
INSTRUCTIONS AND DEFINITIONS

“investigator,” as defined below, on a research or training project must complete his/her section of the Disclosure Form which must then be submitted to the IRB via the eIRB application. This requirement pertains to either funded and unfunded research or training activity. If the project is to be funded, please ensure that conflicts of interest and other requirements related to proposal submissions are followed.

The term "investigator" means:

1. the principal investigator,
2. co-principal investigators, co-investigators, and
3. any other University personnel who, in the course of their association with the University are or will be responsible for the design, conduct, administration, collaboration, analysis and/or reporting of either research or training activities funded or proposed for funding by any sponsor, or of unsponsored research or training activities. These persons may include faculty, non-faculty employees, research associates, technicians, consultants, postdoctoral fellows, graduate and other students.

The term "interest" means any financial or other personal involvement of the investigator, his or her spouse, domestic partner, children, parent, or siblings who reside in the same household including, but not limited to:

1. income; honoraria or other payment for services;
2. reimbursed or sponsored travel for services
3. equity such as stock, stock options or other ownership rights, excluding interests of any amount in publicly traded, diversified mutual funds, pension funds, or other institutional investment funds over which the faculty member does not exercise control;
4. patents and copyrights;
5. contracts, licensing and other agreements;
6. royalties (including those royalties distributed by the University);
7. employment; and services, relationships or positions, even if uncompensated.

If there is a financial or other personal interest requiring disclosure, provide on Part 2 of this form all relevant details about the relationship of the interest to the Investigator’s Institutional responsibilities, and sufficient information for the Conflict of Interest Committee to determine if a conflict of interest exists, and how such a conflict of interest might be managed, reduced or eliminated. Use additional pages if needed. Be as specific as possible.
Provide relevant details related to how the financial or other personal interest identified on Part 2 of this form relates to the proposed research and Investigator's institutional responsibilities: