

Policy and Procedures on Financial Conflict of Interest in Research		
<i>Office of Research and Sponsored Programs</i>		Original Date: August 2, 2012
<i>Research Integrity and Compliance</i>		
Reviewed and Approved by: Office of Research and Sponsored Program Director Research Compliance Officer	Date: May 15, 2017	Revision Date: July 9, 2013 Revision Date: July 13, 2015 Revision Date: May 15, 2017

I. Policy Statement

Montclair State University is committed to preserving the public trust, and upholding the integrity of its faculty, staff, students and affiliates in the design, conduct and reporting of **research**. This policy promotes objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct, and reporting of research performed under a federally sponsored grant or cooperative agreement will be free from bias resulting from investigator **Financial Conflict of Interest**.

Montclair State University faculty and other research personnel, or **“investigators”** may have relationships with entities outside of the University that reasonably appear to be related to their **institutional responsibilities**. In accordance with the Public Health Service (PHS) Policy 42 CFR Part 50 Subpart F, and b) National Science Foundation (NSF) policy **“Notice No. 117**, an investigator’s actual and potential **Significant Financial Interests** (SFI) must be disclosed to the University. If the nature of the significant financial interest is such that it affects (or is perceived to affect) the design, reporting and conduct of federally sponsored research, the University is required to identify, manage, reduce or eliminate the real or perceived financial conflict of interest in a timely manner.

Effective December 26, 2014, the Federal Office of Management and Budget (OMB) Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards, 2 CFR 200.112 requires that “all federal agencies must establish conflict of interest policies for Federal awards.” In consideration of these requirements, this revised FCOI policy is expanded and specific to the conduct of any **“Federally Sponsored Project,”** including research supported by federal flow through funds, and is required since federal requirements are not identical to the financial disclosure obligations required under the State of New Jersey’s Conflict of Interest laws and ethics regulation and guidelines.

This policy in no way abrogates the obligation to independently comply with the New Jersey Conflicts of Interest Laws and ethics requirements and submission of all filings required by such New Jersey laws.

II. Definitions

Entity means any domestic or foreign, public or private, organization (excluding a federal agency) from which an investigator (and investigator's spouse, partner or immediate family) or organization which employs or will employ the investigator (and investigator's spouse, partner or immediate family) receives remuneration or in which any such person(s) has an ownership or equity interest.

Equity interest means any stock, stock option, or otherwise ownership interest as determined through reference to public prices, or other reasonable measures of fair market value.

Federally Sponsored Project means research or any other project funded by an agency or other organizational entity of the government of the United States of America, either directly, or via pass-through from an external organization. (E.g., another university, or other entity.)

Financial Conflict of Interest (FCOI) means a significant financial interest or tangible personal benefit that could directly and significantly impact the design, conduct and reporting of the research or the award of a contract/subcontract.

Financial Interest means anything of monetary value or tangible personal benefit, whether or not the value is readily ascertainable.

Institution means any domestic or foreign, public or private, entity or organization (excluding a Federal agency) that is applying for or that receives PHS and/or NSF research funding.

Institutional Responsibilities means an investigator's professional responsibilities on behalf of the institution, which may include activities such as research, research consultation, teaching, professional practice, institutional committee memberships, procurement of a contract to a third party using the federal funds, and service on panels such as Institutional Review Boards.

Intellectual Property Rights and Interests means receipt of income related to such rights and interests by the investigator and/or the investigator's spouse, partner or immediate family. (e.g., patents, copyrights, trademarks, trade secrets).

Investigator means the project director, principal investigator, or any other person regardless of title or position who is responsible for the design, conduct or reporting of research funded by PHS and/or NSF, or proposed for such funding, which may include collaborators or consultants.

National Science Foundation means the National Science Foundation and its associated Directorates, Divisions and Programs.

Public Health Service means the Public Health Service of the U.S. Department of Health and Human Services, and any components of the PHS to which the authority involved may be delegated, including the NIH.

Remuneration includes salary, and any payment for services not otherwise identified as salary greater than nominal value (e.g., consulting fees, honoraria, paid authorship).

Research means scholarly or scientific investigation or discovery.

Senior/Key Personnel means the Project Director/Principal Investigator (PD/PI) and any other person *identified* as senior/key personnel by the Institution in the grant application, progress report, or any other report submitted to the PHS and/or NSF by the Institution under the regulation.

The term **significant financial interest (SFI)** means **remuneration; equity interests; intellectual property rights and interests** (e.g., patents, copyrights and royalties from such rights) reasonably related to the individual's institutional responsibilities, e.g., research and/or scholarly activities, teaching and advising.

- **Publicly Traded Entities**-A SFI exists if the value of remuneration received by the investigator (and/or his/her spouse, partner or immediate family) by the entity, in the previous 12 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.
- **Non-Publicly Traded Entities**-A SFI exists if the value of any remuneration received by the investigator (and/or his/her spouse, partner or immediate family) in the preceding 12 months, exceeds \$5,000, or when the investigator (and/or the investigator's spouse, partner or immediate family) holds *any* equity interest in the entity.
- **Intellectual Property Rights and Interests (e.g., patents, copyrights)**-A SFI exists upon receipt of income related to such rights and interests by the investigator and/or the investigator's spouse, partner or immediate family.

Investigators also must disclose the occurrence of any reimbursed or sponsored travel (i.e., that which is paid on behalf of the investigator and not reimbursed to the investigator so that the exact monetary value may not be readily available), related to their institutional responsibilities; provided, however, that this disclosure requirement does not apply to travel that is reimbursed or sponsored by a federal, state, or local government agency, or an institution of higher education.

The term SFI does not include:

- salary, royalties or other remuneration from the University;
- nominal income from service on advisory committees or review panels for public or nonprofit entities;
- royalties or other payments from publicly traded entities, when aggregated for the investigator, and the investigator's spouse, partner and immediate family, are not expected to exceed \$5,000 during the previous twelve-month period;
- income from self-authored textbooks, software, etc. that are used for the investigator's teaching purposes;
- travel related or sponsored travel related to institutional responsibilities that is reimbursed by a federal, state, or local government agency, or an institution of higher education as defined at 20 U.S.C. 1001(a);
- income from investment vehicles, such as mutual funds and retirement accounts, as long as the investigator does not directly control decisions made on the investment vehicles;
- income from seminars, lectures or teaching engagements sponsored by and service on an advisory or review panel for federal, state, or local government agency, or other institution of higher education
- unsolicited gifts or items that are of nominal value

A significant financial interest becomes a financial conflict of interest if it could result in personal gain, advantage to others to the detriment of MSU, or influence the design, conduct and reporting of the investigator's research.

Financial Conflict of Interest exists when the University, through its designated official(s), reasonably determines that an investigator's significant financial interest is related to any federally-funded research project and could directly and significantly affect the design, conduct or reporting of the research, or arises in connection with a firm considered for a contract to be paid by federal funds.

III. Procedures

A. Investigator Disclosure

i. Annual Significant Financial Interest Disclosure: In accordance with this policy, all University investigators who are currently supported by federal funding must complete an Annual Significant Financial Interest Disclosure Form. This form must be completed and returned to the Compliance Office on or before October 1st, annually, or within 60 days of appointment. The investigator shall, to the best of his/her knowledge, disclose his/her significant financial interests as well as the significant financial interests of his/her spouse, partner and immediately family that reasonably appear to be related to the investigator's institutional responsibilities. This form is available on the Compliance Office's website (see Appendix A). Upon receipt of each annual or updated disclosure form, the Compliance Administrator will review the disclosure, requesting additional information, as necessary. If no significant financial interests are disclosed, no further review is required and no additional action will be required of the investigator unless a significant change in status occurs prior to the next annual due date. The disclosure form will be retained by the Compliance Office, the central repository for all Annual Significant Financial Interest Disclosure Forms. If a significant financial interest is disclosed, the Director of ORSP will reasonably determine if a real or perceived financial conflict of interest exists that is related to a federally-funded research project and could directly and significantly affect the design, conduct or reporting of the research. If an FCOI is identified, the Director of ORSP will follow the procedure for disclosure of a FCOI. Annual Significant Financial Interest Disclosure Forms will remain on file with the Compliance Office for a period of 3 years, beyond the date of disclosure.

ii. Significant Financial Interest Disclosure for Proposal Submissions: [The university's proposal submission policy](#) requires the Principal Investigator/Project Director to complete and submit to the Research and Sponsored Programs Office (ORSP) an Internal Proposal Routing Form with each proposal submission. Proposal Routing Forms are reviewed and endorsed by each investigator and their Department Chair, Dean and the Director of the ORSP. As is required under this policy, all investigators involved in the design, conduct and reporting of the research must disclose at the time of submission any significant financial interests that reasonably appear to be related to their institutional responsibilities. SFIs will be disclosed using the Significant Financial Interests Disclosure Form (see Appendix B). The Director of ORSP will review each Proposal Routing Form for SFI disclosures. If no significant financial interest are disclosed, no further review is required and no additional action will be required of any investigator unless the proposal is awarded, and a significant change occurs prior to the next annual due date. If an SFI is disclosed by any investigator at the time of proposal submission, the Director of ORSP will reasonably determine if a real or perceived financial conflict of interest exists that is related to the federally-funded research project and could directly and significantly affect the design, conduct or reporting of the research, or to a firm that will or may be award a contract paid from the federal funds. If a financial conflict of interest is identified, the Director of ORSP will follow the procedure for disclosure of a FCOI.

iii. Human and/or Animal Subjects: Investigators submitting a human and/or animal subjects protocol to the Institutional Review Board (IRB) and/or Institutional Animal Care and Use Committee (IACUC) review must file or have on file an Annual Significant Financial Interest Disclosure Form (Appendix A), as well as have completed the Significant Financial Interest Disclosure section of the individual Proposal Routing Form, prior to IRB and/or IACUC review on a federally funded project. Further, any disclosure of Significant Financial Interest on federally funded projects under review for financial conflict of interest will be reported to the Compliance Officer.

- iv. **Change in Significant Financial Interest Status:** Should a new, reportable significant financial interest arise for any investigator during the period of grant funding, an updated Annual Significant Financial Interest Disclosure Form must be submitted to the Compliance Office.

IV. Review and Management of SFI

A. Management of Financial Conflict of Interest

Should an SFI disclosure related to federally sponsored research indicate a real or perceived financial conflict of interest, the Director of ORSP will advise the Provost, and/or his designee. The Director of ORSP will gather further information and supporting documentation from the investigator and refer the FCOI disclosure to the *Financial Conflict of Interest Management Committee* for review and management. *All such documentation and subsequent discussions will be confidential.*

The Conflict of Interest Management Committee will be composed of no less than 3 faculty members, approved by the Provost and/or his designee. The investigator will have the opportunity to meet with the Financial Conflict of Interest Management Committee to explain the financial documentation and FCOI. Should the findings indicate a financial conflict of interest, the Financial Conflict of Interest Management Committee will recommend actions to the Provost and/or his designee, to effectively manage, reduce, or eliminate the conflicts.

Examples of conditions or restrictions that might be imposed to manage an investigator's financial conflict of interest (if any) include, but are not limited to:

- Public disclosure of financial conflicts of interests (e.g., when presenting or publishing the research; to staff members working on the project; to University's Institutional Review Board(s);
- For research projects involving human subjects research, disclosure of financial conflicts of interest directly to participants;
- Appointment of an independent monitor capable of taking measures to protect the design, conduct, and reporting of the research against bias resulting from the financial conflict of interest;
- Modification of the research plan;
- Change of personnel or personnel responsibilities, or disqualifications of personnel from participation in all or a portion of the research;
- Reduction or elimination of the financial interest (e.g., sale of an equity interest); or
- Severance of relationships that create financial conflicts of interest; and/or
- Disciplinary action by the Vice President for Human Resources in consultation with the Provost.

All records of investigator disclosure will remain on file with the Compliance Office for a period of 3 years from the date of the submission of the final expenditures report.

B. Appeal Process

Should the faculty member or other investigator not agree with the Financial Conflict of Interest Management Committee's conditions or restrictions, he/she can appeal in writing to the Provost within ten (10) days after receipt of notification from the Director of ORSP, spelling out why such conditions and restrictions are inappropriate. The Provost and/or his designee will then consult with the Financial Conflict of Interest Management Committee; it is possible that a modification of the conditions and restrictions will be agreeable to all parties. However, the decision of the Provost and/or the Provost's designee is final.

C. Non-Compliance

Whenever an investigator does not disclose in a timely manner, a previously existing significant financial interest or the University fails to review a previously existing significant financial interest during an ongoing federally funded project, the Director ORSP shall, within sixty (60) days: review the significant financial interest and reasonably determine if a real or perceived financial conflict of interest exists that is related to the research project and could directly and significantly affect the design, conduct or reporting of the research, or the award of a contract. If an FCOI is identified, the University must implement, on at least an interim basis, a management plan that shall specify the actions that have been, or will be, taken to manage such financial conflict of interest going forward and submit an FCOI report to the federal awarding agency.

In addition to the FCOI report, the University must, within 120 days of its determination of noncompliance, complete a retrospective review of the investigator's research activities and the federally-funded research project to determine whether any funded research, or portion thereof, conducted during the time period of the noncompliance, was biased in the design, conduct or reporting of such research.

Based on the results of the retrospective review, if appropriate, update the previously submitted FCOI report, specifying the actions that will be taken to manage the financial conflict of interest going forward.

If bias is found, notify the appropriate federal entity promptly and submit a mitigation report that includes the key elements documented in the retrospective review and a description of the impact of the bias on the research project and the University's plan of action or actions taken to eliminate or mitigate the effects of the bias. Thereafter the University will submit FCOI reports annually.

V. Institutional Compliance and Reporting Responsibilities

A. Prior to Award

Prior to spending any funds under an award, the Institution must report to the federal awarding agency the existence of any significant financial conflict of interest and assure that the interest has been managed, reduced, or eliminated in accordance with the regulations. The Institution must also provide an FCOI report whenever an investigator does not timely disclose a Significant Financial Interest or whenever the Institution, for whatever reason, does not review a disclosed Significant Financial Interest and the Institution then determines that a Financial Conflict of Interest exists.

B. Ongoing Projects

The Institution must submit an FCOI report to the federal awarding agency 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.

C. Annual FCOI 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 shall 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 as when the Institution is required to submit the annual progress report (i.e., two months prior to the start date or 45 days prior to the start date of the noncompeting continuation award), including a multi-year funded progress report, or at the time of the extension (e.g., submission of an extension notification in the eRA Commons or

submission of a federal prior approval request, whichever is applicable.) When a conflicting financial interest ceases to exist during the ongoing project period, the Institution should update the status of the Financial Conflict of Interest at the time of the next annual FCOI report submission deadline.

D. Subrecipients

Responsibilities for Research Subrecipients

If required under the terms and conditions of a sponsored Research project, the University will require any written subaward agreement with any organization to include terms establishing the applicable FCOI policy governing the subrecipient's work, whether it is the Montclair State University policy or the policy of the subrecipient institution. The subrecipient will be required to provide certification that its policy is established in accord with sponsor requirements or, if unable to provide such certification, the University policy will be applicable to all subrecipient Investigators. (As a rule, the University will require subrecipient institutions to maintain and administer their own FCOI policies and will only in exceptional circumstances assume primary responsibility for directly soliciting and reviewing subrecipient personnel disclosures that enable the University to directly identify and manage identified FCOIs from the SFI disclosures of subrecipient personnel.) In addition, the written subaward agreement will establish timelines and information requirements that will allow sufficient time for the University to evaluate, as applicable, subrecipient disclosures or subrecipient FCOI reports in order for the University to meet any applicable sponsor reporting requirements.

VI. Training Requirements

A. Investigator Requirements: The PHS revised regulation on FCOI requires that each investigator must complete training prior to engaging in research related to any PHS funded grant, and at least every four years, and immediately under the designated circumstances:

1. University FCOI Policies change in a manner that affects investigator requirement
2. An investigator is new to the University with PHS funding
3. The University finds an investigator noncompliant with the MSU's FCOI policy or management plan

Montclair State University will provide FCOI training for personnel identified on PHS funded research. NSF and other federally sponsored personnel are not required to complete training, but are strongly encouraged to do so.

VII. Public Accessibility to FCOI information

A. Written Response to Requests

In the event of a public request for information on an FCOI, in compliance with PHS Policy, prior to the expenditure of any funds under a PHS-funded research project, MSU will make reasonable efforts to provide accessibility by written response within five business days of a request, of information concerning any significant financial interest disclosed to the University that meets PHS FCOI.

VIII. Federal References

- A. [OMB Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards \(2 CFR Part 200\)](#)**
- [2 CFR 200.112](#)
 - [2 CFR 200.317](#)
 - [Office of Executive Councils, Chief Financial Officers Counsel: Counsel on Financial Assistance Report \(COFAR\)](#)
- B. U.S. Department of Health and Human Services (Including Public Health Service and National Institutes of Health)**
- [42 CFR Part 50, Subpart F, Responsibility of Applicants for Promoting Objectivity in Research for which Public Health Service Funding is Sought](#)
 - [National Institutes of Health Financial Conflict of Interest Page](#)
 - [NIH Tutorial on Financial Conflict of Interest](#)
- B. National Science Foundation**
- [NSF "Investigator Financial Disclosure Policy"](#)
 - [NSF "Frequently Asked Questions Concerning the DHHS Objectivity in Research Regulations and the NSF Investigator Financial Disclosure Policy"](#)
 - [NSF Proposal and Award Policies and Procedures Guide, January 2011, Part II - Award & Administration Guide, Chapter IV, A. Conflict of Interest Policies](#)
 - [NSF Proposal and Award Policies and Procedures Guide, January 2011, Part I - Grant Proposal Guide, Chapter II, C.1.e. Proposal Certifications](#)