Montclair State University
Policy and Procedures on Financial Conflict of Interest in Research

I. Policy Statement

Montclair State University is committed to preserving the public trust and upholding the integrity of the design, conduct and reporting of its Research. This policy promotes objectivity in Research by establishing standards that ensure the design, conduct, and reporting of Research performed under Public Health Service (PHS) and National Science Foundation (NSF) sponsored grants or cooperative agreements will be free from bias resulting from financial conflicts of interest.

This policy applies to Montclair State University faculty, staff and students, and any other University Investigators, who are responsible for the design, conduct and reporting of Research funded or proposed for funding by the PHS and the NSF.

Montclair State University Investigators may have relationships with entities outside of the University that may reasonably appear to be related to their Institutional Responsibilities. In accordance with 1. ) PHS Policy 42 CFR Part 50 Subpart F, and 2.) NSF policy “Notice No. 117, an Investigator’s Significant Financial Interests must be disclosed to the University. If the Significant Financial Interest could directly and significantly affect the design, conduct or reporting of the Research funded by PHS and/or NSF, the University is required to identify, manage, reduce or eliminate the Financial Conflict of Interest in a timely manner.

These guidelines are specific to the conduct of Public Health Service and/or National Science Foundation sponsored Research and required since federal requirements are not identical to the disclosure obligations imposed by New Jersey law. Therefore, compliance with this Policy does not relieve University employees from compliance with its ethical obligations as State of NJ employees.

II. Definitions

Compliance Administrator means the individual at the University that coordinates research compliance matters for the Office of Research and Sponsored Programs (ORSP), the Institutional Animal Care and Use Committee (IACUC), and the Institutional Review Board for Human Subjects (IRB).

Designated Official means the Director of Montclair State University’s Office of Research and Sponsored Programs (ORSP), or its designee.

Entity means any domestic or foreign, public or private, organization (excluding a Federal agency) from which an Investigator (and spouse and dependent children) receives remuneration or in which any person 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.
**Financial Conflict of Interest (FCOI)** means a significant financial interest that could directly and significantly impact the design, conduct and reporting of the Research.

**Financial Interest** means anything of monetary value, 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, and includes Montclair State University.

**Institutional Official** means the Montclair State University Provost, or its designee.

**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, and service on panels such as Institutional Review Boards.

**Intellectual Property Rights and Interests** means income related to rights and interests by the Investigator and/or the Investigator’s spouse and dependents to patents, copyrights, trademarks, trade secrets, inventions or discoveries from the Research.

**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 otherwise identified as salary (e.g., consulting fees, honoraria, paid authorship).

**Research** means scholarly or scientific investigation or discovery.

**Senior/Key Personnel** means any 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, which may include but not be limited to the Investigator.

The term **Significant Financial Interest** means Remuneration, Equity Interest, Intellectual Property Rights and Interests, reasonably related to the Investigator’s institutional responsibilities, e.g. research, scholarly activities, teaching and advising. Significant Financial Interests include but are not limited to the following:

- **Publicly Traded Entities**-A Significant Financial Interest exists if the total aggregate value of remuneration received by the Investigator, the Investigator’s Spouse and/or the Investigator’s dependent children from an Entity during the 12 months preceding the disclosure exceeds $5,000.
- **Non-Publicly Traded Entities**-A Significant Financial Interest exists if the total value of any remuneration received by the Investigator, the Investigator’s Spouse and/or the Investigator’s dependent children during the preceding 12 months exceeds $5,000 or when the Investigator, Investigator’s Spouse or Investigator’s dependent children holds any equity Interest in the Entity.
- **Intellectual Property Rights and Interests**-A Significant Financial Interest exists upon receipt of ownership to such rights and interests by the Investigator and/or the Investigator’s spouse and dependent children.
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 Significant Financial Interest does not include:**

- salary, royalties or other remuneration from the University;
- 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, Investigator’s spouse and the Investigator’s dependent children, are not expected to exceed $5,000 during the previous twelve-month period;
- income from self-authored textbooks, software, etc. that are used for your 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.

A Significant Financial Interest becomes a Financial Conflict of Interest if it could result in personal gain, advantage to others to the detriment of the Institution, or influence the design, conduct and reporting of the Investigator’s Research.

**Financial Conflict of Interest** means the University, through its Designated Official, reasonably determines that an Investigator’s Significant Financial Interest is related to a PHS and/or NSF-funded Research project and could directly and significantly affect the design, conduct or reporting of the Research.
III. Procedures

A. Mandatory Investigator Disclosures

i. Significant Financial Interest Disclosure for PHS and NSF Proposal Submissions: Investigators shall complete and submit to the University’s Research and Sponsored Programs Office (ORSP) an internal Proposal Routing Form with each proposal submission. Proposal Routing Forms are reviewed and endorsed by the Investigator, Department Chair, Dean and the Designated Official. As is required under PHS and NSF policy, Investigators shall disclose at the time of submission any Significant Financial Interests. Significant Financial Interests will be disclosed using the Proposal Significant Financial Interest Disclosure Form. The Designated Official will review each Proposal Routing Form for Significant Financial Interest disclosures. If no Significant Financial Interest is disclosed, no further review is required and no additional action will be required of the Investigator unless the proposal is awarded, and a significant change occurs prior to the next annual due date. If a Significant Financial Interest is disclosed by an Investigator at the time of proposal submission, the Designated Official will determine if the Significant Financial Interest identified in the disclosure is related to the Investigator’s PHS and/or NSF sponsored Research. If the Significant Financial Interest is related to the Investigator’s PHS and/or NSF sponsored Research, the Designated Official will refer the disclosure to the Financial Conflict of Interest Management Committee.

ii. Significant Financial Interest Disclosure for PHS and NSF Awards: In accordance with PHS and NSF policy, the Investigator must complete a Significant Financial Interest Disclosure Form during the period of award. This form must be completed and returned to the Compliance Administrator on or before October 1st, annually, and within 30 days of acquiring a new Significant Financial Interest, or within 60 days of appointment. The Investigator shall disclose all Significant Financial Interests held by the Investigator, the Investigator’s spouse and the Investigator’s dependent children. This form is available on the Compliance Administrator’s website. Upon receipt of each annual or updated disclosure form, the Compliance Administrator will review the form for Significant Financial Interest disclosures. 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 disclosure date. The disclosure form will be retained by the Compliance Administrator in the central repository for all awarded Significant Financial Interest Disclosure Forms. If a Significant Financial Interest is disclosed on the Significant Financial Disclosure Form, the Compliance Administrator will forward the disclosure to the Designated Official. The Designated Official will determine if the Significant Financial Interest identified in the disclosure is related to the Investigator’s PHS and/or NSF sponsored Research. If the Significant Financial Interest is related to the Investigator’s PHS and/or NSF sponsored Research, the Designated Official will refer the disclosure to the Financial Conflict of Interest Management Committee.

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 submit a Proposal Significant Financial Interest Disclosure Form, as well as the Significant Financial Interest Disclosure section of the Proposal Routing Form, prior to IRB and/or IACUC review on a PHS and/or NSF funded project. Further, any disclosure of Significant Financial Interest on PHS and/or NSF funded projects under review for Financial Conflict of Interest will be reported to the Compliance Administrator.
iv. **Change in Significant Financial Interest Status:** Should the Investigator, Investigator’s spouse, or Investigator’s dependent children acquire a Significant Financial Interest after the submission of the Significant Financial Interest Disclosure Form to the Compliance Administrator, the Investigator shall report same within 30 days of such acquisition by the filing of an updated Significant Financial Interest Disclosure Form to the Compliance Administrator.

v. **Maintenance of Records.** The Compliance Administrator shall maintain records of all financial disclosures and all actions taken to resolve actual or potential Financial Conflicts of Interests for 3 years after the later of the termination of the PSH or NSF contract, completion of the Research to which such contracts relate, or the resolution of any government action involving these records.

**IV. Review and Management of SFI associated with a PHS/NSF award**

A. **Management of Financial Conflict of Interest**

Should a Significant Financial Interest related to an Investigator’s PHS and/or NSF sponsored Research be disclosed, the Designated Official will advise the Institutional Official, and/or the Institutional Official’s designee.

The Designated Official will gather further information and supporting documentation from the Investigator and refer the Significant Financial Interest disclosure to the Financial Conflict of Interest Management Committee for review and management. All such documentation and subsequent discussions will be confidential to the extent permitted by applicable law.

The Financial Conflict of Interest Management Committee will be comprised of no less than 3 faculty members, approved by the Institutional Official. The Investigator will have the opportunity to meet with the Financial Conflict of Interest Management Committee to discuss the Significant Financial Interest disclosure. Should the Committee find a Financial Conflict of Interest, the Committee will recommend action to the Institutional Official to effectively manage, reduce, or eliminate the conflict.

Examples of conditions or restrictions that the Committee may impose to manage a Financial Conflict of Interest include, but are not limited to:

- Public disclosure of Investigator’s Significant Financial Interests (including but not limited to, when presenting or publishing the results of 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 Significant Financial Interests 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 the portion of the Research that would be affected by the Significant Financial Interest;
- Divestiture of the Significant Financial Interest (including but not limited to, sale of the equity interest and/or stock, withdrawal from a partnership, withdrawal as a member of a limited liability company); or
- Severance of relationships that create actual or potential financial conflicts of interest.
B. Appeal Process
Should the Investigator not agree with the Financial Conflict of Interest Management Committee’s conditions or restrictions, the Investigator can appeal in writing to the Institutional Official within ten (10) days after receipt of notification from the Designated Official, spelling out why such conditions and restrictions are inappropriate. The Institutional Official will then consult with the Financial Conflict of Interest Management Committee to determine whether a modification of the conditions and restrictions will be feasible. However, the decision of the Institutional Official is final.

C. Non-Compliance and Retrospective Review
A Financial Conflict of Interest may not be identified or managed in a timely manner, due to:

1.) Failure of the Investigator to disclose a Significant Financial Interest that is determined to constitute a Financial Conflict of Interest
2.) Failure by the University to Review or Manage a Conflict of Interest
3.) Failure by the Investigator to comply with a Financial Conflict of Interest Management Plan

In that event, the University shall, within 120 days of its determination of noncompliance with this policy, complete a retrospective review of the Investigator’s activities and the PHS and/or NSF funded Research project to determine whether the Research, or portion thereof, conducted during the time period of non-compliance was biased in the design, conduct, or reporting of such research. The Designated Official shall, within sixty (60) days of being notified of the Significant Financial Interest, determine if the Significant Financial Interest is related to the Investigator’s PHS and/or NSF sponsored Research. If so, the Designated Official shall, within 30 days after identifying the Significant Financial Interest refer the disclosure to the Financial Conflict of Interest Committee for review and management.

Within 30 days after completing the retrospective review, the Designated Official shall inform PHS and/or NSF of the findings of the Financial Conflict of Interest Committee. If bias is found, the Designated Official shall promptly notify PHS and/or NSF, as applicable, and submit a mitigation report that includes key elements of the retrospective review, a description of the impact of the bias on the Research, and the University’s plan to impose conditions or restrictions that will eliminate or mitigate the effects of the bias. Thereafter the University’s Designated Official will submit Financial Conflict of Interest reports annually.

V. Institutional Compliance and Reporting Responsibilities
A. Prior to Award
Prior to the expenditure of any funds awarded by PHS or NSF, the University’s Designated Official must report to the NIH the existence of any Financial Conflict of Interest and assure that the interest has been managed, reduced, or eliminated in accordance with all applicable regulations. The Designated Official shall also provide a Financial Conflict of Interest report to PHS and/or NSF if it is discovered that the Investigator has not timely disclosed a Significant Financial Interest or if the Institution failed to determine that a Financial Conflict of Interest existed.

B. Ongoing Projects
The Designated Official shall submit a Financial Conflict of Interest report to the NIH within sixty (60) days after it determines that an FCOI exists.
C. Annual FCOI Report
For any Financial Conflict of Interest previously reported by the University, the Designated Official shall provide an annual Financial Conflict of Interest report that includes the status of the Significant Financial Interest and any changes to the University’s plan to manage it. Annual Financial Conflict of Interest reports shall identify whether the Financial Conflict of Interest is being managed or provide an explanation of why the Financial Conflict of Interest no longer exists. Annual Financial Conflict of Interest reports must be submitted to the PHS and/or NSF during the duration of the grant contract or performance of the Research, whichever is later, on the date when the University is required to submit its 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 NIH eRA Commons or submission of a PHS and/or NSF prior approval request, whichever is applicable.) When a Financial Conflict of Interest ceases to exist during the ongoing project period, the Designated Official shall update the status of the Financial Conflict of Interest at the time of the next annual Financial Conflict of Interest report submission deadline.

D. Subrecipients
Prior to submission of a proposal to PHS and/or NSF, or issuance of a subaward agreement, the University shall ensure that the proposed recipient of any subaward under PHS and/or NSF sponsored Research agrees to comply with PHS and/or NSF policies on Financial Conflict of Interest. If the proposed subrecipient does not have a publicly posted Financial Conflict of Interest Policy in compliance with PHS and/or NSF policy, the subrecipient will be required to comply with University policy.

Subrecipients will be required to report Financial Conflicts of Interest to the University’s Designated Official within 45 days of discovering the Financial Conflict of Interest. Should a Subawardee Investigator report a Financial Conflict of Interest, the University’s Designated Official will report the Financial Conflict of Interest to the PHS on the subrecipient’s behalf.

VI. Training Requirements
A. Investigator Requirements: Investigators shall attend training offered by the University prior to engaging in Research funded by PHS, and again thereafter at least every four years. In addition, Investigators shall undergo training offered by the University immediately under the following circumstances:

1. University FCOI Policies change in a manner than affects Investigator requirements;
2. An Investigator was recently hired by the University and has received PHS funding;
3. The University determines the Investigator has failed to comply with this policy and/or any condition or restriction imposed due to the presence of an FCOI;

Montclair State University will provide Financial Conflict of Interest training for personnel identified on PHS funded Research. University employees who are conducting NSF sponsored Research are not required to complete the training, but are encouraged to do so since the PHS revised requirements are very similar to current NSF requirements.
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, University Counsel 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 Financial Conflict of Interest.

VIII. Federal References

A. 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"