



NORTHWESTERN
UNIVERSITY

Responsible University Official: Provost
Responsible Office: Northwestern
University Conflict of Interest Office
(NUCOI)
Origination Date: August 24, 2012

CONFLICT OF INTEREST IN RESEARCH

Policy Statement

As noted in Northwestern University's [*Policy on Conflict of Interest and Conflict of Commitment*](#), the University encourages its Faculty, Students and Staff to participate in research activities and to do so with the highest ethical standards. While the potential for Conflicts of Interest to arise is understandable, Investigators must strive to limit introduction of bias into their research. Faculty who are involved in outside consulting or business activities must clearly separate their University and outside obligations in order to avoid concerns as to their appropriate use of University resources and contributions by other University personnel. Faculty members must be open about their involvement with and obligations to outside parties and should provide students, Staff and colleagues with information about the funding that supports their research.

Reason for Policy/Purpose

The University encourages its Faculty, Students and Staff, as appropriate, to seek research funding from internal and external sponsors. As external sponsors establish their own policies regarding Conflict of Interest, the University is expected to oversee compliance with these regulations for any of its personnel seeking funding from a particular sponsor. This Policy, along with the University's [*Policy on Conflict of Interest and Conflict of Commitment*](#), establishes the University's compliance framework and promotes objectivity in research.

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Who Approved This Policy

Provost
Senior Vice President for Business and Finance
Vice President for Research

Who Needs to Know This Policy

Faculty, Staff and all other members of the Northwestern University research community

Website Address for This Policy

Website: http://www.northwestern.edu/coi/policy/research_policy.pdf

Contacts

If you have any questions with regards to the policy or procedures e-mail:
nucoi@northwestern.edu

Definitions

All definitions used in the [Policy on Conflict of Interest and Conflict of Commitment](#) apply to this Policy.

Policy/Procedures

1.0 Guiding Principles

External research sponsors, and the University, seek to promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct and reporting of research, including that supported by grants, cooperative agreements and contracts, will be free from bias resulting from Investigator Financial Conflicts of Interest. In particular, the Public Health Service (PHS) has promulgated regulations on “Promoting Objectivity in Research.”¹ This Policy is premised on the PHS regulations.

Northwestern personnel who submit applications for funding to more than one external sponsor will be held to the most stringent standards of the various sponsors to which they apply. To the extent that such standards are more stringent than this Policy or the University’s [Policy on Conflict of Interest and Conflict of Commitment](#), the sponsor’s requirements will take precedence.

A list of external sponsors subject to Northwestern’s COI requirements can be found in the following section of the Northwestern Conflict of Interest website: [Research Sponsors Subject to Northwestern’s Research Conflict of Interest \(COI\) Disclosure Requirements](#).

2.0 To Whom Does This Policy Apply

Any individual acting as a “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” is an Investigator and must satisfy the disclosure requirements of this Policy.² Faculty and Staff must also comply with the University’s [Policy on Conflict of Interest and Conflict of Commitment](#). For purposes of this Policy, the definition of “Investigator” includes the following:

2.1 Faculty

Faculty³ who function or are designated as project director, principal investigator or as key personnel on an application for research support (or any other report) submitted to an external source. Faculty who assume independent responsibility for portions of another Investigator’s proposed or funded project will also be required to meet the disclosure requirements of this Policy, whether that other Investigator is at Northwestern or another institution.

2.2 Staff

Staff members who assume independent responsibility for portions of an Investigator’s proposed or funded project. In addition, Staff who are to be paid from funding obtained by a Faculty member and who receive compensation from an outside entity owned or

¹ See 42 CFR Part 50, Subpart F and 45 CFR Part 94.

² See 42 CFR 50.603.

³ Per the University’s *Policy on Conflict of Interest and Conflict of Commitment*, Adjunct Faculty meeting the definition of Investigator are subject to the disclosure requirements set forth in this Policy.

controlled by the Faculty member will be required to meet the disclosure requirements of this Policy.

2.3 Postdoctoral and Clinical Fellows

Postdoctoral and clinical fellows who assume independent responsibility for portions of an Investigator's proposed or funded project and fellows who seek independent funding for themselves from external sources. In addition, fellows who are to be paid from funding obtained by a Faculty member and who receive compensation from an outside entity owned or controlled by the Faculty member will be required to meet the disclosure requirements of this Policy.

2.4 Graduate Students

While it is anticipated that most graduate students will not be subject to the disclosure requirements of this Policy, graduate students with independent responsibility for portions of an Investigator's proposed or funded project are covered by this Policy. In addition, graduate students who are to be paid from funding obtained by a Faculty member and who receive compensation from an outside entity owned or controlled by the Faculty member will be required to meet the disclosure requirements of this Policy.

3.0 Disclosure Requirements for Investigators

3.1 What Must Be Disclosed Under This Policy?

Investigators are required to disclose any Significant Financial Interest (SFI) to the University. A SFI is any Financial Interest that meets the following criteria:

- (1) A Financial Interest consisting of one or more of the following interests of the Investigator (and those of the Investigator's Immediate Family Member) that reasonably appears to be related to the Investigator's University responsibilities (i.e., an Investigator's responsibilities on behalf of the University, such as research, teaching and institutional committee memberships):
 - a. With regard to any publicly traded entity, a SFI exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure and the value of any equity interest in the entity as of the date of disclosure, when aggregated for the Investigator and members of his or her Immediate Family, exceeds \$5,000. For purposes of this definition, remuneration includes salary and any payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorship); equity interest includes any stock, stock option or other ownership interest, as determined through reference to public prices or other reasonable measures of fair market value;
 - b. With regard to any non-publicly traded entity, a SFI exists if the value of any

remuneration received from the entity in the twelve months preceding the disclosure, when aggregated for the Investigator and members of his or her Immediate Family, exceeds \$5,000, or when the Investigator (or the Investigator's Immediate Family Member) holds any equity interest (e.g., stock, stock option, or other ownership interest); or

- c. Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests. SFI does not include intellectual property rights assigned to the University or agreements to share in the royalties related to such rights.

- (2) For PHS-funded Investigators, SFI also includes the occurrence of reimbursed or sponsored travel related to their University responsibilities received in the twelve months preceding the disclosure, if when aggregated for the Investigator (or members of his or her Immediate Family) from a single entity, exceeds \$5,000. This includes that which is paid on behalf of the Investigator (or members of his or her immediate family) but not reimbursed directly, so that the exact monetary value may not be known. In such circumstances, an estimate of the sponsored travel must be disclosed.

This disclosure requirement, however, does not apply to travel that is reimbursed or sponsored by a federal, state or local government agency, a qualifying institution of higher education, an academic teaching hospital, a medical center or a research institute that is affiliated with an institution of higher education. The details of this disclosure will include, at a minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration.

SFI does **NOT** include:

- (1) Salary, royalties or other remuneration paid by the University to the Investigator if the Investigator is currently employed or otherwise appointed by the University;
- (2) Intellectual property rights assigned to the University and agreements to share in royalties related to such rights;
- (3) Income from investment vehicles, such as mutual funds and retirement accounts, as long as the Investigator does not directly control the investment decisions made in these vehicles;
- (4) Income from seminars, lectures or teaching engagements sponsored by a federal, state or local government agency, a qualifying institution of higher education, an academic teaching hospital, a medical center or a research institute that is affiliated with a qualifying institution of higher education; or
- (5) Income from service on advisory committees or review panels for a federal, state or local government agency, a qualifying institution of higher education, an academic teaching hospital, a medical center or a research institute that is

affiliated with a qualifying institution of higher education.

3.2 When is Disclosure Required?

SFIs are to be initially disclosed at the proposal stage, and must be disclosed on an ongoing basis within 30 days of discovery or acquisition of a new SFI and at least annually. Investigators will disclose SFIs in the FASIS system, which allows for the electronic filing and management of these disclosures.

3.3 How are Disclosures Reviewed?

Schools will review disclosed SFIs to determine if the SFI creates a Financial Conflict of Interest (FCOI), which is a SFI that could directly and significantly affect the design, conduct or reporting of research. The University's school-based conflict of interest committees will establish standards that provide a reasonable expectation that the design, conduct and reporting of research will be free from bias resulting from FCOIs. The schools will review all Investigator SFIs, together with the specific aims of the proposed or awarded project(s) and the appropriate disclosure thresholds, to determine if the SFI rises to the level of a FCOI. If it does, the schools will work with University personnel to develop a plan to manage, reduce or eliminate the FCOI. Investigators whose primary appointment is in a University Research Center will be subject to the same review process as non-Center Investigators, but conducted by the University Conflict of Interest Oversight Committee (COIOC), rather than an individual school-based committee.

Access to information collected in connection with this Policy will be limited to those with a need to know and will be shared in accordance with University policy and federal regulation.

3.4 Are FCOIs Reported Outside the University?

Some external sponsors, such as PHS, require the University to provide initial and ongoing reports on an Investigator's FCOI to the sponsor. The University will provide sponsors with FCOI information as required by individual sponsor policy. In addition, external sponsors, such as PHS, obligate the University to make available to the public, upon request, information regarding FCOIs for senior and key personnel. The reporting and ongoing management of FCOIs to external sponsors and the reporting to the public of FCOIs for senior and key personnel will be the responsibility of the University Conflict of Interest Office.

4.0 Special Note for Investigators Seeking Industry Sponsorship for Research and Clinical Trials

The conflict of interest committees must approve any proposed industry sponsored research study when a Conflict of Interest may exist, and integrity must be protected by the establishment of an appropriate management plan in the following types of situations:

- (1) A Faculty member is involved in research involving his or her inventions/creations;

- (2) A company licensed to use a Faculty member's invention/creation is sponsoring the research;
- (3) A Faculty member's Immediate Family Member has a Financial Interest in the outcome of the research.

The University will require disclosures from all Investigators who are proposing or participating in an industry sponsored research project. However, reporting SFIs for industry based research projects will be set at the zero dollar threshold. If the conflict of interest committee determines that the interest, whether financial or otherwise, represents a FCOI, the committee will work with the Investigator to develop a plan to manage, reduce or eliminate the conflict.

5.0 Roles and Responsibilities

5.1 School Conflict of Interest Committees

The University's school-based conflict of interest committees will establish standards that provide a reasonable expectation that the design, conduct and reporting of research will be free from bias resulting from FCOIs. The schools will review all Investigator SFIs, together with the specific aims of the proposed or awarded project(s) and the appropriate disclosure thresholds, to determine if the SFI rises to the level of a FCOI. If it does, the schools will work with University personnel to develop a plan to manage, reduce or eliminate the FCOI.

5.2 University Conflict of Interest Office

The Northwestern University Conflict of Interest Office (NUCOI) reports to the Office of the Provost. The NUCOI Office will be responsible for policy development and implementation, training and education. The NUCOI will also interact with and receive periodic updates from the school-based conflict of interest committees, as well as the Staff Conflict of Interest Committee, and will be responsible for reporting FCOIs to external sponsors and to the public when required.

5.3 Conflict of Interest Oversight Committee

The Provost has created a Conflict of Interest Oversight Committee (COIOC) comprised of representatives from each of the schools of the University and from central administration. The role of the COIOC includes resolution of potential Conflicts of Interest arising through annual or periodic disclosures that cross school or Faculty/Staff boundaries or from within University-level research centers, oversight of management plans brought to the COIOC's attention by the schools, and other steps needed to ensure consistent application of this Policy throughout the University. The COIOC will also interact with and receive periodic updates from any school-based conflict of interest committee, as well as the Staff Conflict of Interest Committee. Furthermore, the COIOC will oversee and recommend changes, as needed, to the University's [Policy on Conflict of Commitment and Conflict of Interest](#) and this Policy.

5.4 Staff Conflict of Interest Committee

The Staff Conflict of Interest Committee may review SFI disclosures from Staff members acting in the capacity of Investigators, and interact with the NUCOI and COIOC as needed.

6.0 Appeal Process

For the process on appeals, refer to sections 5.3 and 10.0 of the [Policy on Conflict of Interest and Conflict of Commitment](#).

7.0 Noncompliance

The following are examples of noncompliance with this Policy:

- a) Failure to submit a disclosure report;
- b) Submission of an incomplete, erroneous or misleading initial, updated or annual disclosure report;
- c) Failure to disclose information as required by this Policy; or
- d) Failure to comply with prescribed management plans.

Instances of noncompliance will be decided in accordance with applicable University disciplinary policies and procedures.

For instances of noncompliance involving PHS proposals and awards, whenever a FCOI is not identified or managed in a timely manner, including failure by the Investigator to disclose a SFI, or failure to comply with the management plan, the University must complete a retrospective review of the Investigator's activities on the project to determine if there is bias in the design, conduct or reporting of the research resulting from the FCOI. The University must also promptly notify PHS and submit a mitigation report when bias is found.

Forms/Instructions

Please visit: www.northwestern.edu/coi to access the FASIS Portal

Related Information

[Northwestern University Policy on Conflict of Interest and Conflict of Commitment](#)

[Research Sponsors Subject to Northwestern's Research Conflict of Interest \(COI\) Disclosure Requirements](#)

[Public Health Service, "Promoting Objectivity in Research," 42 CFR Part 50, Subpart F](#)

[Public Health Service, "Responsible Prospective Contractors," 45 CFR Part 94](#)

[National Institutes of Health Financial Conflict of Interest Tutorial](#)

History/Revision Dates

Origination Date: August 24, 2012

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