



NORTHWESTERN
UNIVERSITY

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

Policy on Conflict of Interest in Research

Policy Statement

As noted in Northwestern's *Policy on Conflict of Interest and Conflict of Commitment*, the University encourages its faculty, staff, and students to participate in research activities and to do so with the highest ethical standards. While the potential for conflicts of interest to arise in research is understandable due to the innovative and entrepreneurial pursuits of our research community, we must identify and manage situations in which financial or other personal interests could bias or compromise – or have the appearance of biasing or compromising – objectivity or judgment relative to research. Faculty who are involved in outside consulting or business activities must clearly separate their Northwestern and outside obligations in order to avoid concerns as to their appropriate use of University resources and contributions by other Northwestern 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

Northwestern encourages its faculty, staff, and students, as appropriate, to seek research funding from internal and external sponsors. As external sponsors establish their own policies regarding conflict of interest, Northwestern is expected to administer and oversee compliance with these requirements. This Policy, along with Northwestern's *Policy on Conflict of Interest and Conflict of Commitment*, promotes objectivity in research and establishes the University's conflict of interest compliance framework.

Who Approved This Policy

Provost
Executive Vice President
Vice President for Research

Who Needs to Know This Policy

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

Website Address for This Policy

Website: <http://www.northwestern.edu/coi/policy/index.html>

Contacts

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

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Definitions

All definitions used in the *Policy on Conflict of Interest and Conflict of Commitment* also apply to this Policy, along with those listed below, which specifically apply to this *Policy on Conflict of Interest in Research*:

Entity: For the purposes of this Policy, an Entity is an external business, company, or other such organization, and includes (but is not limited to) any partnership, corporation, limited liability corporation, unincorporated association, or other institution or organization, whether for-profit, academic, or professional.

Financial Conflict of Interest: For the purposes of this Policy, a Financial Conflict of Interest exists when Northwestern, through its designated official(s), reasonably determines that an Investigator's Significant Financial Interest is related to a funded research project and could directly and significantly affect the design, conduct or reporting of the funded research, or present the appearance thereof.

Immediate Family Member: For the purposes of this Policy, Immediate Family Member includes an Investigator's spouse, domestic or civil union partner, and dependent children.

Institutional Responsibilities: For the purposes of this Policy, Institutional Responsibilities include professional activities that relate to an Investigator's responsibilities on behalf of Northwestern, such as research, teaching, institutional committee memberships, professional practice, and administrative activities and responsibilities for Northwestern.

Investigator: For the purposes of this policy, Investigator includes anyone responsible for the design, conduct, or reporting of research, regardless of title or position, and their Immediate Family Members.

Significant Financial Interest: For the purposes of this Policy, a Significant Financial Interest includes an external financial interest consisting of one or more of the following interests of an Investigator (and those of the Investigator's Immediate Family Members) *related to their Institutional Responsibilities*, when combined for the 12 months preceding the disclosure date, from a single Entity:

Nature of Significant Financial Interest	Disclosure Threshold
Remuneration, compensation, and/or other payments for services (e.g., consulting, speaking)	Exceeds \$5,000 ¹
Equity interests in a publicly-traded entity	Exceeds \$5,000
Equity interests in a non-publicly-traded entity (e.g., a start-up company)	0 / Any
Intellectual property rights and interests	Exceeds \$5,000 ¹
Sponsored or reimbursed travel	Exceeds \$5,000 ¹

Disclosure of sponsored or reimbursed travel applies to PHS funded researchers only

1. Investigators whose primary appointment is in the Feinberg School of Medicine (FSM) are subject to a zero dollar disclosure threshold for remuneration, intellectual property interests, and sponsored or reimbursed travel, meaning that regardless of the \$5,000 remuneration disclosure threshold identified above, FSM faculty must report any remuneration, intellectual property interests, or sponsored or reimbursed travel greater than zero.

Significant Financial Interests do NOT include:

- (1) Salary, royalties or other remuneration paid by Northwestern to the Investigator if the Investigator is currently employed or otherwise appointed by the University;
- (2) Intellectual property rights assigned to Northwestern and agreements to share in royalties related to such rights;
- (3) Equity interests through 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;
- (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; or
- (6) Sponsored or reimbursed travel sponsored or paid 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.

Subrecipient: For the purposes of this Policy, a Subrecipient is a legal entity that receives a Subcontract from a pass-through entity to carry out a portion of a sponsored program. A Subrecipient has responsibility for programmatic decision making; has its performance measured in relation to whether objectives of a programmatic scope of work were met; and is responsible for adherence to applicable sponsored program requirements specified in the sponsored award, as opposed to providing routine goods or services for the benefit of the pass-through entity.

Policy/Procedures

1.0 Guiding Principles

Northwestern, and external research sponsors, seek to promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct and reporting of research will be free from bias resulting from financial interests.

2.0 Applicability

Investigators who submit applications for research funding to any federal or industry sponsors, or other sponsors that have conflict of interest requirements, and/or Investigators engaged in research involving human research participants, regardless of funding source, are subject to the training, disclosure, review, and management requirements of this Policy unless otherwise specified in this Policy. Investigators funded by the Public Health Service (PHS) and/or other agencies that abide by PHS COI regulations¹ are subject to additional requirements as specified in this Policy.

Faculty and Staff must also comply with Northwestern's *Policy on Conflict of Interest and Conflict of Commitment*.

To the extent that any external sponsor's standards are more stringent than this Policy or the Northwestern's *Policy on Conflict of Interest and Conflict of Commitment*, the sponsor's requirements will take precedence.

3.0 Training

Investigators involved in research funded by sponsors subject to this Policy must complete required conflict of interest training before engaging in research and every four years thereafter. Northwestern may require training more frequently than every four years if there is a substantive conflict of interest Policy change or specific instances of noncompliance.

4.0 Disclosure

4.1 What Must Be Disclosed?

Investigators are required to disclose any Significant Financial Interests that reasonably appear to be related to the Investigator's Institutional Responsibilities. For the purposes of this Policy, a Significant Financial Interest includes an external financial interest consisting of one or more of the following interests of an Investigator (and those of the Investigator's Immediate Family Members), related to their Institutional Responsibilities, when combined for the 12 months preceding the disclosure date, from a single Entity:

Nature of Significant Financial Interest	Disclosure Threshold
Remuneration, compensation, and/or other payments for services (e.g., consulting, speaking)	Exceeds \$5,000 ¹
Equity interests in a publicly-traded entity	Exceeds \$5,000
Equity interests in a non-publicly-traded entity (e.g., a start-up company)	0 / Any
Intellectual property rights and interests	Exceeds \$5,000 ¹
Sponsored or reimbursed travel	Exceeds \$5,000 ¹

Disclosure of sponsored or reimbursed travel applies to PHS-funded researchers only

1. Investigators whose primary appointment is in the Feinberg School of Medicine (FSM) are subject to a zero dollar disclosure threshold for remuneration, intellectual property interests, and sponsored or reimbursed travel, meaning that regardless of the \$5,000 remuneration disclosure threshold identified above, FSM faculty must report any remuneration, intellectual property interests, or sponsored or reimbursed travel greater than zero.

Significant Financial Interests do NOT include:

- (1) Salary, royalties or other remuneration paid by Northwestern to the Investigator if the Investigator is currently employed or otherwise appointed by the University;
- (2) Intellectual property rights assigned to Northwestern and agreements to share in royalties related to such rights;
- (3) Equity interests through 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;

- (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; or
- (6) Sponsored or reimbursed travel sponsored or paid 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.

4.2 Who Must Disclose?

Any individual responsible for the design, conduct, or reporting of research covered under this Policy, regardless of title or position, is an Investigator and must satisfy the requirements of this Policy. For purposes of this Policy, individuals meeting the definition of Investigator may include faculty, staff, postdoctoral and clinical fellows, graduate students, and/or others who assume independent responsibility for the design, conduct, or reporting of research covered under this Policy. The Principal Investigator is responsible for designating which individuals involved in specific research activities meet the definition of Investigator.

4.3 When is Disclosure Required?

Investigators must disclose Significant Financial Interests prior to engaging in research, within 30 days of discovery or acquisition of a new Significant Financial Interest, and at least annually during the annual Faculty and Staff conflict of interest disclosure processes (even if acknowledging no change to previous disclosures). Investigators must perform initial and ongoing disclosures of Significant Financial Interests in Northwestern's conflict of interest disclosure system.

5.0 Review

Significant Financial Interests are reviewed by Northwestern's Conflict of Interest Office (NUCOI) in conjunction with applicable School Dean's Offices and/or conflict of interest committees in the context of each research project on which an individual is an Investigator. Conflict of interest reviews take into account the nature and extent of an Investigator's role on a project, the nature and extent of an Investigator's Significant Financial Interest(s), and the nature of the research activity under review. These reviews are conducted to assess whether or not Significant Financial Interests of an Investigator relate to and could directly and significantly affect the design, conduct, or reporting of research, thus presenting a Financial Conflict of Interest relative to the research, or an appearance thereof.

NUCOI performs an initial review of all Investigator disclosures of Significant Financial Interests relative to all applicable research projects. NUCOI may make determinations, on a research project by research project basis, that an Investigator's Significant Financial Interests do not relate to nor have the ability to directly and significantly affect the design, conduct, or reporting of the research, or NUCOI may refer reviews to the School in which the Investigator holds a primary appointment for further evaluation and disposition.

Any Significant Financial Interests that have the potential to present a Financial Conflict of Interest for any research project are referred by NUCOI to the applicable School for review and disposition. Designated individuals in each Schools' Dean's Office then review the Significant Financial Interest(s) to determine whether or not the Significant Financial Interest presents a Financial Conflict of Interest for the related research activity. Reviews for Investigators whose primary appointment is in a University Research Center will be conducted by NUCOI or Northwestern's Conflict of Interest Oversight Committee (COIOC), rather than a School Dean's Office or an individual School-based committee. The determination of whether or not a Significant Financial Interest represents a Financial Conflict of Interest may occur by designated individuals in the Schools' Dean's Offices, School-based conflict of interest committees, or the COIOC. Individual matters or reviews may be referred to the COIOC at any time by NUCOI, School Dean's Offices, or School-based conflict of interest committees.

Reviews and determinations must occur prior to expenditure of funds for new projects and within 60 days of newly-disclosed Significant Financial Interests. Additionally, reviews and determinations must occur within 60 days of the addition of new Investigators to projects during the life of a project.

6.0 Management

If a Financial Conflict of Interest determination is made, School Dean's Offices, School-based conflict of interest committees, the COIOC, and/or NUCOI (working with Investigators and others as needed) develop a conflict of interest management plan to manage, reduce, or eliminate the Financial Conflict of Interest. Conflict of interest management plans are strategies designed to mitigate the potential for an Investigator's Significant Financial Interests to impact or bias research objectivity and/or the safety or welfare of human research participants.

Conflict of interest management plans could include disclosure of the Financial Conflict of Interest (to study teams, collaborators, the Institutional Review Board, human research participants, and in presentations and publications), a reduced role in the research, and/or independent review of research data and results. Additional conflict of interest management strategies may be employed depending on the nature of the Financial Conflict of Interest and the nature of the research activity. In extreme cases, an Investigator may be prohibited from participating in research due to the level and extent of Significant Financial Interests deemed to present a Financial Conflict of Interest relative to specific research activity.

Investigators must acknowledge agreement to conflict of interest management plans in order to engage in research for which Financial Conflict of Interest determinations are made.

Financial Conflict of Interest determinations are made, and conflict of interest management plans implemented, by designated applicable institutional conflict of interest officials/parties (i.e. NUCOI, School Dean's Offices, School-based conflict of interest committees, or the COIOC). However, it is in the purview of Northwestern's Institutional Review Board (IRB) to review the conflict of interest management strategies associated with IRB protocols and determine whether or not the conflict of interest management is sufficient with respect to the rights and welfare of human research participants, or whether the IRB determines that additional conflict of interest management is necessary to protect the rights and welfare of human research participants. The IRB is notified of Financial Conflict of Interest determinations made, and conflict of interest management strategies implemented, relative to research involving human research participants.

The conditions of and compliance with Investigator conflict of interest management plans are reviewed on at least an annual basis by School Dean's Offices and NUCOI. On an ad hoc basis, NUCOI also conducts independent monitoring and verification to ensure that the conditions of conflict of interest management plans are being met.

7.0 Appeals

For information on appealing determinations regarding Financial Conflicts of Interest or conflict of interest management, refer to sections 5.3 and 10.0 of the *Policy on Conflict of Interest and Conflict of Commitment*.

8.0 External Reporting

NUCOI administers and oversees all external conflict of interest reporting for Northwestern in accordance with federal and individual sponsor requirements.

Some external sponsors, such as PHS, require Northwestern to provide initial and ongoing reports relative to Investigator's Financial Conflict of Interest determinations as they relate to specific research activities. For Financial Conflicts of Interests relative to PHS-funded research, NUCOI must perform the required conflict of interest reporting prior to the expenditure of funds for new projects, within 60 days of newly-determined Financial Conflicts of Interest identified during the life of a project, and on an annual basis thereafter prior to progress report submission during the life of a project.

In addition, PHS requires Northwestern to make available to the public, upon request, specific information regarding Financial Conflicts of Interest determined for senior and key personnel relative to PHS-funded research. NUCOI is required to provide specific information relative to such public requests within five business days of the request.

9.0 Subrecipients

Northwestern must apply relevant originating sponsor conflict of interest requirements to subrecipients. Therefore, Northwestern must identify whether or not a subrecipient has a conflict of interest policy compliant with applicable originating sponsor conflict of interest requirements. If a subrecipient does not have a conflict of interest policy compliant with applicable originating sponsor conflict of interest requirements, in order

to proceed with the Northwestern collaboration, the subrecipient must agree to abide by this Policy relative to the subrecipient investigators and the specific subrecipient research activity for the duration of that activity. The subrecipient agreement must incorporate terms that establish whether the conflict of interest policy of Northwestern or that of the subrecipient will apply to subrecipient investigators, and obligations of the subrecipient relative to conflict of interest in either case.

10.0 Noncompliance

The following are examples of noncompliance with this Policy:

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

Any instances of Investigator noncompliance may require that the Investigator repeat Northwestern's required conflict of interest training module. Additional disciplinary action for noncompliance with this Policy will be decided in accordance with applicable Northwestern disciplinary policies and procedures as outlined in the Faculty Handbook, the Staff Handbook, and other relevant policies. Ramifications for noncompliance could include restrictions relative to proposing and engaging in Northwestern research and/or an internal review of the research, as well as other disciplinary action up to and including termination.

For instances of noncompliance involving PHS-funded research, whenever a Financial Conflict of Interest is not identified or managed in a timely manner, including failure by the Investigator to disclose a Significant Financial Interest, or failure of an Investigator to comply with the conditions of a conflict of interest management plan, Northwestern must conduct a retrospective review of the Investigator's research activities on the project to determine if there is bias in the design, conduct, or reporting of the research resulting from the Financial Conflict of Interest. The retrospective review must be completed within 120 days of the determination of noncompliance. If bias is found in the course of the retrospective review, Northwestern must promptly notify PHS and submit a mitigation report that addresses the impact of the bias on the research and the University's plan of action to eliminate or mitigate the effect of the bias.

Additionally, for instances of noncompliance noted above involving PHS-funded clinical research whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment, the Investigator is thereafter required to disclose the Financial Conflict of Interest in each public presentation of the results of the relevant research and also request an addendum to previously published presentations of the relevant research.

11.0 Confidentiality

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 Northwestern policies and federal regulations.

12.0 Record Retention

Conflict of interest records relative to research covered under this Policy must be maintained for a period of three years after any applicable research project's final financial report is submitted to the sponsor, or until three years after the final action has been taken on any audit, litigation, or claim. Please refer to the *Policy on Retention of University Records, Appendix A*.

13.0 Roles and Responsibilities

13.1 Investigators

Investigators are responsible for engaging in research design, conduct, and reporting that is free from bias resulting from conflicts of interest. Investigators have an obligation to meet initial and ongoing conflict of interest training and disclosure requirements and comply with the conditions of conflict of interest management plans, if applicable.

13.2 Northwestern Conflict of Interest Office

Northwestern's Conflict of Interest Office (NUCOI) oversees and implements the University's faculty, staff, research, and institutional conflict of interest policies and procedures, ensures compliance with applicable conflict of interest regulatory requirements, provides guidance and support to the Northwestern community regarding conflict of interest policies, systems, standards, and procedures, and administers and supports the activities of the COIOC and the Staff Conflict of Interest Committee. NUCOI administers conflict of interest training and disclosure requirements University-wide, performs initial reviews of Investigators' Significant Financial Interests in the context of research activities, and refers reviews to Schools or the COIOC for further evaluation and disposition. The Director of NUCOI is Northwestern's institutional official for conflict of interest and fulfills Northwestern's conflict of interest reporting requirements to federal agencies, external sponsors, and the public when required. NUCOI performs ongoing compliance monitoring of the conflict of interest requirements detailed in this Policy, the *Policy on Conflict of Interest and Conflict of Commitment*, and the *Policy on Institutional Conflict of Interest in Research*. NUCOI may escalate reviews, disputes, or issues to the COIOC at any time.

13.3 School Dean's Office Designees and School-based Conflict of Interest Committees

Schools are responsible for promoting and facilitating research design, conduct, and reporting that is free from bias resulting from conflicts of interest. Designated individuals in each School Dean's Office and School-based conflict of interest committees, if applicable, perform reviews referred from NUCOI of Investigators' Significant Financial Interests relative to applicable research projects. Schools make determinations, on a research project by research project basis, whether or not Investigators' Significant Financial Interests present conflict of interest concerns. If a Financial Conflict of Interest determination is made, Schools work with Investigators and others as needed to develop a conflict of interest management plan to manage, reduce, or eliminate the Financial Conflict of Interest. Schools review conflict of interest

management plans of Investigators on at least an annual basis. Schools may escalate reviews, disputes, or issues to the COIOC at any time.

13.4 Conflict of Interest Oversight Committee (COIOC)

The role of the Provost’s Conflict of Interest Oversight Committee (COIOC) includes review and resolution of institutional conflicts of interest, as well as conflict of interest issues arising through annual or periodic disclosures that cross school or Faculty/Staff boundaries or involving Faculty and/or Investigators in University-level research centers, and conflict of interest matters referred from NUCOI, School Dean’s Offices, or School-based conflict of interest committees. The COIOC interacts with and receives periodic updates from School-based conflict of interest committees and the Staff Conflict of Interest committee. The COIOC also ensures consistent application of this Policy throughout the University. Furthermore, the COIOC oversees and recommends changes, as needed, to this Policy, Northwestern’s *Policy on Conflict of Commitment and Conflict of Interest*, and the *Policy on Institutional Conflict of Interest in Research*. The COIOC is comprised of representatives from each of the Schools of Northwestern and from key relevant offices within central administration.

13.5 Staff Conflict of Interest Committee

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

Forms/Instructions

<http://www.northwestern.edu/coi/index.html>

Related Information

[*Northwestern University Policy on Conflict of Interest and Conflict of Commitment*](#)
[*Northwestern University Policy on Institutional Conflict of Interest in Research*](#)
[*Northwestern University Faculty Handbook*](#)
[*Northwestern University Staff Handbook*](#)
[*Northwestern University Policy on Subcontracting on Sponsored Programs*](#)
[*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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