

Volume code:	Code Financial Conflicts of Interest for Public Health Services (PHS) Investigators	Responsible Office: Office of Research and Sponsored Projects
		Responsible Officer: Director of Office of Research and Sponsored Projects

POLICY STATEMENT

Northeastern Illinois University requires that PHS-funded investigators disclose any significant financial interest that would reasonably appear to affect sponsored research. Specifically, researchers funded by PHS must disclose significant financial interests (SFIs) that are reasonably related to the research or to an investigator's University responsibilities that in any way could bias the design, conduct or implementation, management, and reporting of research data. The University will have a mechanism for the investigators to disclose SFIs and University-designated officials to determine if an SFI represents a Financial Conflict of Interest (FCOI). Determination of the existence of an FCOI will lead to the development of a University-approved management plan to manage or eliminate the FCOI. The disclosure and management of the FCOI will occur before the University releases any funds to investigators for expenditure.

PURPOSE OF THE POLICY

The University has a responsibility to manage, reduce, or eliminate any actual or potential conflicts of interest that may be presented by a financial interest of an investigator, who is seeking, or who has been awarded, research funding.

This interim policy on financial conflicts of interest was developed to comply with the 2011 Public Health Services (PHS) Regulations, Department of Health and Human Services 42 CFR Part 50 and 45 CFR Part 94, on Financial Conflicts of Interest (FCOI) that went into effect on August 24, 2012. These revisions to the Administrative Memorandum of 2004, "Significant Financial Disclosure Policy for Sponsored Research Investigators", increase accountability, add transparency, and enhance regulatory compliance and effective Institutional management of investigators' financial conflicts of interest. The primary goal of this policy is 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 Investigator financial conflicts of interest.

WHO IS AFFECTED BY THIS POLICY

Members of the Northeastern Illinois University community who are involved in research.

DEFINITIONS

A **Financial Conflict of Interest (FCOI)** is a significant financial interest that reasonably appears to be related to the Investigator's institutional responsibilities. In particular, a significant financial interest that could reasonably appear to be related to a research program or project, so could directly and significantly affect the design, conduct or reporting of that research, including the protection of human research subjects. The FCOI of an Investigator includes any FCOI's of the Investigator's family members.

Institutional Responsibilities are an Investigator's professional responsibilities on behalf of the university including, but not limited to, activities such as research, consultation, teaching, professional practice, institutional committee membership, and service on panels such as Institutional Review Boards.

An **Investigator** is any person responsible for the design, conduct, or reporting of the research. This includes, but is not limited to, the Principal Investigator, Faculty Sponsor, co-investigators, or other key

research personnel. An investigator may be a Teaching Professional, Instructor, Resource Professional, or Academic Support Professional, a staff member, student, administrator, unpaid personnel (including volunteers) or other individual who engages the University in research involving human subjects pursuant to the review and approval of the IRB; or is otherwise identified as involved in research by a Principal Investigator or another University administrative officer responsible for research activities.

Family members include the investigator's spouse or domestic partner, parents, siblings, and children.

Research is any systematic investigation designed to develop or contribute to generalizable knowledge. The term encompasses basic and applied research and product testing and development. It includes any activity for which research funding is available from an external sponsor that awards funds under grants, cooperative agreements, or otherwise.

A **Significant Financial Interest (SFI)** is any of the following:

1. The value of any remuneration received from an external entity at present or in the 12 months preceding the disclosure that when aggregated for the investigator and family members totals or exceeds \$5,000. The \$5,000 threshold also applies to salary, royalties, and other payments aggregated for the investigator and family members.
2. The value of a publicly traded equity (plus any remuneration) meets or exceeds \$5,000.
3. Any level of ownership in a privately held equity regardless of the dollar value.
4. Intellectual property rights (e.g., patents, trademarks, copyrights, licensing agreements, and royalties from such rights.)
5. Any other relationships that might present a conflict of interest, such as fiduciary interests (paid or unpaid positions as director, officer, or other management role in a for-profit or not-for-profit entity sponsoring or related to the research) or interests in which compensation or the value of equity or property rights or the combination of interests might affect the outcome of the research.
6. 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, an Institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education.

The following list of **SFI's** are exempt from the disclosure requirements:

1. Salary, royalties or other remunerations paid by Northeastern Illinois University;
2. Income from investment vehicles (mutual funds or retirement accounts that are not managed directly by the individual);
3. Income from seminars, lectures, or teaching engagements sponsored by a Federal, state, or local government agency, an Institution of higher education as defined by 20 U.S.C. 1001(a); an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education;
4. Income from service on advisory committees or review panels for a Federal, state, or local government agency, or an Institution of higher education as defined by 20 U.S.C. 1001(a). (e.g., NIH review panel)

REGULATIONS

2011 Public Health Services (PHS) Regulations, Department of Health and Human Services (HHS) 42 CFR Part 50 and 45 CFR Part 94, on Financial Conflicts of Interest (FCOI), which went into effect on August 24, 2012.

Northeastern Illinois University will offer training on Financial Conflicts of Interest to all investigators writing PHS proposals.

All NEIU investigators funded by PHS must comply with the following requirements:

1. Disclose their SFIs over the previous twelve-month period to NEIU no later than at the time of the application for externally funded research.

2. Submit an updated disclosure of SFIs at least annually, no later than January 15th, during the period of award.
3. Submit an updated disclosure of SFIs within 30 days of discovering or acquiring a new SFI.
4. Complete FCOI training provided by NEIU prior to the expenditure of funds for any funded project. Thereafter training must be completed at least every four years and immediately when:
 - a. NEIU Financial Conflict of Interest policies change in a manner that affects investigator requirements
 - b. An investigator is new to NEIU
 - c. NEIU finds that an investigator is not in compliance with this Financial Conflict of Interest policy or a management plan.
5. Comply with any management plan requirements and any monitoring of that management plan conducted by NEIU.

Principal Investigator Responsibilities

The principal investigators are responsible for ensuring and certifying that each key personnel on a PHS proposal has disclosed his/her SFIs. They are also responsible for ensuring and certifying that each investigator has completed the mandatory NEIU FCOI training.

Institutional Responsibilities

The Office of Research and Sponsored Projects (ORSP) will collect and perform an initial review of all disclosed SFIs to determine if an FCOI exists. The ORSP may submit an FCOI to a committee for review in complex cases. After a determination is made by the ORSP that there may be a potential or actual FCOI, the ORSP will develop a management plan (see below) to address the FCOI.

These plans will be developed collaboratively and examples of conditions or restrictions that may be employed to manage conflicts include but are not limited to:

- Public disclosure of significant financial interests (e.g., when presenting or publishing the research), if appropriate to the discipline;
- Disclosure of significant financial interests directly to participants involved in human research;
- Appointment of an independent monitor capable of taking measures to protect the design, conduct, and reporting of research;
- Modification of research plan;
- Change of personnel or personnel responsibilities or disqualification from participation in all or a portion of the research;
- Reduction or elimination of the financial interest (e.g., sale of an equity interest);
- Severance of relationships that create the actual or potential conflict of interest; or
- If it proves impossible to develop an acceptable management plan, funds will be returned to the sponsor.

If an investigator has an FCOI and is working on research involving human subjects, then the IRB must be notified of any management plan.

Appeals

An investigator may appeal the ORSP's recommendation to the Dean of the College of Graduate Studies and Research. An investigator dissatisfied with his/her appeal may submit his/her disagreement in writing to the Provost for final resolution.

Reporting

Prior to expenditure of any funds, or within 60 calendar days for any interest that NEIU identifies as conflicting subsequent to NEIU's initial report under a PHS-funded research project, NEIU must provide the PHS Awarding Component with a Financial Conflict of Interest (FCOI) report regarding the related FCOI and implemented Management Plan. This report must include the following information:

- Grant/Contract Number
- Project Director/Principal Investigator (PD/PI) or contact PD/PI
- Name of investigator with FCOI
- Nature of the FCOI (e.g., equity, consulting fees, or honoraria)
- Whether the financial interest was managed, reduced or eliminated
- Value of the financial interest

- Description of how FCOI relates to PHS-funded research and the basis for the University's determination that the financial interest conflicts with such research.
- Key elements of the Management Plan

Annual updates are also required for the duration of the research project and must include:

- Status of the FCOI
- Changes to the management plan

Non-Compliance

When an investigator is found to have violated this policy or the terms of the management plan, the university may impose sanctions consistent with NEIU policy. Disciplinary action may vary from a warning to termination of employment. In cases of violation, the Dean of the College of Graduate Studies and Research will notify the appropriate funding agency.

Retrospective Review

Identification of untimely or any delayed disclosure of an SFI by an investigator requires NEIU's review within 60 days of determination, if it is related to PHS-funded research and if an FCOI exists. Determination that there is an unmanaged FCOI requires:

- 1) Implementation – at least in the interim – of a management plan that specifies the actions that have been and will be taken to manage the FCOI moving forward; and
- 2) Completion of a retrospective review of the Investigator's activities and the PHS-funded research to determine whether any PHS-funded research, or a portion of it, conducted during the noncompliance period was biased in the design, conduct or reporting of such research within 120 days of the Investigator's noncompliance. Such noncompliance may have occurred due to the Investigator's failure to disclose an SFI deemed an FCOI, NEIU's failure to review or manage said FCOI, or the Investigator's failure to comply with a management plan.

Mitigation Report

As appropriate, NEIU shall update a previously submitted FCOI report specifying the actions taken to manage the FCOI moving forward. If NEIU determines there was bias, it must notify the PHS awarding component promptly and submit a mitigation report to that component. The mitigation report must include:

- 1) The key elements documented in the retrospective review and a description of the impact of the bias on the research project and the institution's actions/action plan to eliminate or mitigate the effect of the bias;
- 2) Subsequently the institution will submit annual reports, as per the regulation. Depending on the nature of the FCOI the institution may decide that additional interim measures are necessary regarding the Investigator's participation in the PHS-funded research project between the date of the FCOI or the Investigator's noncompliance is determined and the completion of the institution's retrospective review.

Records

Records of the Investigator's significant financial interests and NEIU's review and management of the SFI, will be retained by the university for (i) three years from the date of submission of the final expenditures report (in the case of grants and cooperative agreements); or (ii) three years from the final payment (in the case of research contracts), or (iii) resolution of any government action involving the records, or (iv) as otherwise required by law.

Public Accessibility

In accordance with PHS regulations, NEIU will respond to requests regarding financial conflicts of interest by written response within five business days of a request. The response shall include the Investigator's name, position relative to the research project, the name of the entity in which the SFI is held, nature of the SFI, approximate dollar value of SFI, or a statement that the value cannot be readily determined.

Subrecipients

For PHS research that involves subcontractors, subgrantees or subawardees (collectively "subrecipients") at other institutions, the NEIU requires written agreement terms from subrecipients that they have a conflict of interest policy that conforms to the requirements of all applicable regulations, including time periods to meet disclosure and/or financial conflict of interest (FCOI) reporting requirements.

If any subrecipient does not have such a conflict of interest policy, then NEIU shall require that Subrecipient follow the NEIU's policy, and Subrecipient's failure to promptly do so upon request from NEIU shall be considered to be grounds for immediate termination by NEIU of any applicable subcontract or sub-award. Any written agreement terms required by the NEIU shall contain the provision that Subrecipients will report to NEIU as the awardee Institution, any identified FCOI in sufficient time to allow NEIU to report the FCOI to meet its reporting obligations.

PROCEDURES

GUIDELINES

AUTHOR REFERENCE

For the 2011 NIH regulations on Financial Conflicts of Interest, see:

<http://grants.nih.gov/grants/policy/coi/>

For discussion of the revisions to PHS policy related to Financial Conflicts of Interest:

<https://www.federalregister.gov/articles/2011/08/25/2011-21633/responsibility-of-applicants-for-promoting-objectivity-in-research-for-which-public-health-service>

For answers to frequently asked questions about the 2011 revised regulation:

http://grants.nih.gov/grants/policy/coi/coi_faqs.htm#3181

Much of the material for this policy is based on the policies on Financial Conflict of Interest at Northern Illinois University (NIU) and the Policy on Conflict of Commitment and Interest at the University of Illinois. Links to these policies:

<http://www.niu.edu/divresearch/integrity/fcoi.shtml>

<http://research.uillinois.edu/coci/coci-policy>

HISTORY

APPENDIX

RELATED POLICIES, DOCUMENTS, AND LINKS

Northeastern Illinois University's INTERIM Significant Financial Interests Disclosure Form (NEIU interim SFIDF)

CONTACT INFORMATION

Please direct questions or concerns about this policy to:

Contact	Phone	E-Mail
Director of the Office of Research and Sponsored Projects	4672	ORSP@neiu.edu

DISCLAIMER



The University reserves the right to modify or amend sections of this policy at any time at its sole discretion. This policy remains in effect until such time as the Responsible Officer calls for review. Requests for exception to any portion of this policy, but not to the policy statement, must be presented in writing to the Responsible Officer.