Policy: Financial Conflicts of Interest in Research for Public Health Services (PHS)
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Introduction

Northern Illinois University (NIU) and its employees are asked to assist in a broad range of regional engagement and economic development activities, to work on projects that involve support from the governmental and the commercial sectors, and to engage in consulting relationships and other outside economic activities. Generally, such outside activities enhance professional development, scholarship, and teaching and are strongly encouraged. Along with these benefits, the arrangements between external enterprises and the University, its employees, or students, can potentially create financial conflicts of interest.

A financial conflict of interest (FCOI) occurs when there is a divergence between an individual's private interests and his or her professional obligations to the University, such that an independent observer might reasonably question whether the individual's professional actions or decisions are determined by considerations of personal financial gain. A financial conflict of interest depends on actual situational conditions and the respective roles of the personnel who may be involved, but not on perceptions of the individual's moral character.

This policy supplements NIU’s Conflicts of Interest (COI) Policy in order to provide a more detailed explanation of the FCOI requirements for NIU PHS-funded investigators in accordance with 42 CFR 50, Subpart F, and 45 CFR 94.

Definitions

“Financial Conflict of Interest” means a significant financial interest that is related to a research program or project and could directly and significantly affect the design, conduct or reporting of that research.

“Institutional Responsibilities” means the 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 or Data and Safety Monitoring boards.

“Investigator(s)” means the principal investigator/project director, co-principal investigator, and any other person who is responsible for or involved in the design, conduct, or reporting of research, instructional or service activities funded, or proposed for funding, by an external sponsor. For the purposes of the requirement relating to financial interest, investigator includes spouses and dependent children.
“**Research**” means 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 a Public Health Service component that awards funds under grants, cooperative agreements, or otherwise.

“**Research Conflict Review Committee**” (RCRC) refers to the ad-hoc University committee that advises the Vice President for Research and Innovation Partnerships (VPR) on conflict of interest matters in research. The VPR (or a designee) will appoint the committee members the committee will be made up of no more than five (5) individuals from broad academic disciplines with considerable experience in their respective fields.

“**Significant Financial Interest**” means, except as otherwise specified in this definition:

1. A financial interest consisting of one or more of the following interests of the Investigator (and/or those of the Investigator’s spouse and/or dependent children) that reasonably appears to be related to the Investigator’s institutional responsibilities:

   a. With regard to any publicly traded entity, a *significant financial interest* 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 the disclosure, when aggregated, 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, travel reimbursement). Equity Interests 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 *significant financial interest* exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure, when aggregated, exceeds $5,000, or the Investigator (or the Investigator’s spouse or dependent children) holds *any* equity interest.

   c. Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.

2. For PHS-funded investigators, any reimbursed travel or sponsored travel (i.e., that which is paid on behalf of the Investigator so that the exact monetary value may not be readily available) related to their institutional responsibilities.

3. The term *significant financial interest* **does not** include the following types of financial interests:
a. Salary, royalties, or other remuneration paid by NIU to the Investigator if the Investigator is currently employed or otherwise appointed by NIU, including intellectual property rights assigned to NIU and agreements to share in royalties related to such rights; 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;

b. Income from seminars, lectures, or teaching engagements sponsored by a Federal, state or local agency, an Institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education;

c. Income from service on advisory committees or review panels for a federal, state or local government agency, an Institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education.

d. For PHS-funded investigators, travel that is reimbursed or sponsored by a Federal, state, or local government agency, an Institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education.

Requirements

All NIU PHS-funded investigators must comply with the following requirements:

1. Disclose their SFI over the previous twelve-month period to their institution no later than at the time of the application for PHS-funded research.
2. Submit an updated disclosure of SFI at least annually, no later than January 15th, during the period of award.
3. Submit an updated disclosure of SFI within 30 days of discovering or acquiring a new SFI.
4. Complete FCOI training provided by NIU prior to the expenditure of funds for any funded project. Thereafter training must be completed at least every four years and immediately when:
   a. Institutional Financial Conflict of Interest policies change in a manner that affects investigator requirements
   b. An investigator is new to NIU
   c. NIU 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 NIU.

Principal Investigator Responsibilities
The principal investigators are responsible for ensuring and certifying that each NIU investigator on the PHS proposal has disclosed his/her SFIs. They are also responsible for ensuring and certifying that each investigator has completed the mandatory NIU FCOI training.

**Institutional Responsibilities**

The Office of Research Compliance and Integrity (ORCI) will collect and perform an initial review of all disclosed SFIs to determine if a FCOI exists. If ORCI believes a conflict exists the Research Conflict Review Committee (RCRC) may be assembled to advise the VPR in regards to actual conflicts as well as the approval of management plans (see below).

After a determination is made that there may be a potential or actual FCOI, the ORCI and the investigator will develop a management plan to address the FCOI.

These plans will be developed collaboratively and examples of conditions or restrictions that may be employed to manage conflicts include:

- 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 reach an acceptable Management Plan, funds will be returned to the sponsor.

The determination of an FCOI as well as any management plan must be approved by the VPR. If an investigator has a FCOI and is working on research involving human subjects the IRB must be notified of any management plan.

**Appeals**

An investigator may appeal the ORCI’s recommendation to the VPR. 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 NIU identifies as conflicting subsequent to the NIU’s initial report under a PHS-funded research project, NIU 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 ORCI may impose sanctions consistent with NIU policy. Disciplinary action may vary from a warning to termination of employment. In cases of violation, the Vice President for Research (or designee) will notify the appropriate funding agency.

**Retrospective Review**

Identification of untimely or any delayed disclosure of an SFI by an investigator requires NIU’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 which is deemed an FCOI, NIU’s failure to review or manage said FCOI, or the Investigator’s failure to comply with a management plan.
Mitigation Report

As appropriate, NIU shall update the previously submitted FCOI report specifying the actions taken to manage the FCOI moving forward. If the institution 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 NIU’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, NIU 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 NIU 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 NIU shall require that Subrecipient follow the NIU’s policy, and Subrecipient’s failure to promptly do so upon request from NIU shall be considered to be grounds for immediate termination by NIU of any applicable subcontract or sub-award. Any written agreement terms required by the NIU shall contain the
provision that Subrecipients will report to NIU as the awardee Institution, any identified FCOI in sufficient time to allow NIU to report the FCOI to meet its reporting obligations.