

# FINANCIAL CONFLICT OF INTEREST DISCLOSURE FOR RESEARCH

**POLICY NUMBER:** RESERVED FOR FUTURE USE

**POLICY TYPE:** HYBRID - ACADEMIC/ADMIN

**RESPONSIBLE OFFICIAL TITLE:** DIRECTOR, OFFICE OF RESEARCH, GRANTS, AND CONTRACTS

**RESPONSIBLE OFFICE:** OFFICE OF RESEARCH, GRANTS, AND CONTRACTS

**EFFECTIVE DATE:** 5/4/2017

**NEXT REVIEW DATE:** 5/4/2021

**SUPERSEDES POLICY DATED:** N/A

**REQUIRES LEGAL/COMPLIANCE REVIEW:**

(PER SECTION V. OF THE APPROVED POLICY REQUEST FORM)  YES  NO

**REQUIRES I.T. POLICY COUNCIL REVIEW:**

(PER SECTION V. OF THE APPROVED POLICY REQUEST FORM)  YES  NO

**REQUIRES PROFESSIONAL CONCERNS COMMITTEE REVIEW:**

(PER SECTION V. OF THE APPROVED POLICY REQUEST FORM)  YES  NO

**REQUIRES FACULTY SENATE APPROVAL:**

(PER SECTION V. OF THE APPROVED POLICY REQUEST FORM)  YES  NO

**REQUIRES HUMAN RESOURCES REVIEW:**

(PER SECTION V. OF THE APPROVED POLICY REQUEST FORM)  YES  NO

**REQUIRES BOARD OF REGENTS APPROVAL:**

(PER SECTION V. OF THE APPROVED POLICY REQUEST FORM)  YES  NO

## I. POLICY STATEMENT

Northern Kentucky University has a responsibility to identify, manage, reduce, and/or eliminate research conflicts of interest and/or conflicting financial interests related to research. It is the purpose of this policy to define such conflicts, identify those individuals who must report such conflicts, clarify the potential for such conflicts, and delineate the proper procedures for reviewing and addressing all conflicts of interest. As of August 24, 2012, all institutions accepting federal funding from a grant, cooperative agreement or contract from a Public Health Service (PHS) agency are required to implement and adhere to an Institutional Research Financial Conflict of Interest policy.

## II. ENTITIES AFFECTED

This NKU Institutional policy applies to all researchers/Investigators funded by Public Health Services (PHS) and National Science Foundation (NSF) at NKU.

## III. AUTHORITY

This policy implements federal requirements pertaining to "Objectivity in Research for which Public Health Service (PHS) Funding is Sought" promulgated by the U.S. Public Health Service, which includes the National Institutes of Health (NIH), and which are published in 42 CFR Part 50 and 45 CFR Part 94. This policy also implements federal requirements contained in the National Science Foundation's (NSF) "Investigator Financial Disclosure Policy".

[Public Health Service 42 CFR Part 50 Subpart F and 45 CFR Part 94](#)

[National Science Foundation's \(NSF\) "Investigator Financial Disclosure" Policy](#)

## IV. DEFINITIONS

Among the definitions listed at 42 CFR 50.603 are eight key definitions that you must know in order to understand the Financial Conflict of Interest (FCOI) regulation. They are Institution, Investigator, Institutional Responsibilities, Financial Interest, Financial Conflict of Interest, Manage, and Significant Financial Interest.

Institution refers to any domestic or foreign, public or private, entity or organization (excluding a Federal agency) that is applying for or that receives PHS/NSF and other federal agency research funding.

Institutional Responsibilities means an Investigator's professional responsibilities on behalf of the Institution, and as defined by the Institution, including, but not limited to, activities such as research, research consultation, teaching, professional practice, institutional committee memberships, and service on panels such as Institutional Review Boards or Data and Safety Monitoring Boards.

Investigator as defined by NKU, means the Principal Investigator, Project Director, and any other person, regardless of title or position, who is responsible for or involved in the design, conduct, or reporting of research who are funded by PHS or NSF. This may include collaborators or consultants

Financial Interest means anything of monetary value, whether or not the value is readily ascertainable.

Financial Conflict of Interest (FCOI) means a significant financial interest that could directly and significantly affect the design, conduct, or reporting of research.

Manage means taking action to address a financial conflict of interest, which can include reducing or eliminating the financial conflict of interest, to ensure, to the extent possible, that the design, conduct, and reporting of research will be free from bias.

Significant Financial Interest (SFI) is defined by the regulation as:

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

1. 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 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); 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;

2. 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 when the Investigator (or the Investigator's spouse or dependent children) holds any equity interest (e.g., stock, stock option, or other ownership interest); or

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

B. 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, 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 Institution's FCOI policy will specify the details of this disclosure, which will include, at a minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration. In accordance with the Institution's FCOI policy, the institutional official(s) will determine if further information is needed, including a determination or disclosure of monetary value, in order to determine whether the travel constitutes an FCOI with the PHS-funded research.

A Significant Financial Interest (SFI) of the Investigator's spouse, dependent children, or persons who share financial interests of which could reasonably influence professional responsibilities is required to be included in the initial disclosure prior to submission for funding.

Note: The term significant financial interest does not include the following types of financial interests: salary, royalties, or other remuneration paid by the Institution to the Investigator if the Investigator is currently employed or otherwise appointed by the Institution, including intellectual property rights assigned to the Institution and agreements to share in royalties related to such rights; any ownership interest in the Institution held by the Investigator, if the Institution is a commercial or for-profit organization; 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; income from seminars, lectures, or teaching engagements 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; or income from service on advisory committees or review panels for 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.

## V. RESPONSIBILITIES

Provost and Executive Vice President for Academic Affairs: Institutional Official Responsible for maintaining University compliance.

Director of the Office of Research, Grants and Contracts (RGC), Research Compliance Manager in RGC: Responsible for enforcing NKU research policy procedures to maintain Investigator compliance.

## VI. PROCEDURES

Per Federal regulations; all universities accepting federally sponsored research funds must, at a minimum, enforce a University FCOI policy that requires all Investigators, which include *faculty, staff, and students* conducting research to:

- Complete a Financial Conflict of Interest Disclosure form (FCID) at the time of proposal submission, annually, and as Investigator financial situations change.
- Complete required FCOI training in the CITI training database prior to the expenditure of funds and every four years thereafter.
- When necessary: Adhere to reporting requirements should there be a significant financial conflict of interest, with an approved Management Plan.

See the [Northern Kentucky University Office of Research, Grants, and Contracts](#) website for procedures and forms related to this policy.

## VII. REPORTING REQUIREMENTS

When a Research Financial Conflict of Interest is deemed “significant”, the Institutional Official shall be responsible for reporting requirements in accordance with each funding agency. Reporting requirements vary with agencies. Typically, reporting requirements include reporting at initial disclosure, and then annually until completion of the project. Additionally, Institutions are required to maintain all Research Financial Conflict of Interest program enforcement data to be available upon request for audit from funding agencies.

## VIII. TRAINING

Pursuant to Federal regulations, the Institutional Official or designee, shall inform each Investigator about this regulation and of his/her responsibilities to comply. Prior to engaging in research at NKU, each Investigator shall complete training regarding the disclosure of significant financial interests and the management, reduction or elimination of financial conflicts of interest related to research. Training shall be repeated at least every four years or when (a) this regulation is substantially revised; (b) an Investigator is new to the University; or (c) if an Investigator is determined to not be in compliance with this regulation.

See the [Northern Kentucky University Office of Research, Grants, and Contracts](#) website for specific procedures related to training for this policy.

## IX. COMMUNICATIONS

This policy should be communicated to the Provost, all Vice Provosts, all Deans, all Chairs, all faculty, staff, and students who supervise or are directly involved in research or programmatic projects sponsored by outside funders.

## X. REFERENCES AND RELATED MATERIALS

### REFERENCES & FORMS

See the [Northern Kentucky University Office of Research, Grants, and Contracts](#) website for procedures and forms related to this policy.

### RELATED POLICIES

[Department of Health and Human Services “Objectivity in Research for which Public Health Service \(PHS\) Funding is Sought” promulgated by the U.S. Public Health Service 42 CFR Part 50 and 45 CFR Part 94](#)

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

[National Science Foundation’s \(NSF\) “Investigator Financial Disclosure” Policy](#)

### REVISION HISTORY

REVISION TYPE	MONTH/YEAR APPROVED
<b>New Policy</b>	5/2017
Choose an item.	
Choose an item.	
Choose an item.	
Choose an item.	
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