

# FINANCIAL CONFLICT OF INTEREST DISCLOSURE FOR RESEARCH

**POLICY NUMBER:** ADM-FCOI

**POLICY TYPE:** ADMINISTRATIVE

**RESPONSIBLE OFFICIAL TITLE:** PROVOST & EXECUTIVE VICE PRESIDENT FOR ACADEMIC AFFAIRS

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

**EFFECTIVE DATE:** UPON PRESIDENTIAL APPROVAL – 2/19/2020

**NEXT REVIEW DATE:** PREVIOUS REVISION PLUS FOUR (4) YEARS – 5/14/2027

**SUPERSEDES POLICY DATED:** 5/4/2017

**BOARD OF REGENTS REPORTING (CHECK ONE):**

PRESIDENTIAL RECOMMENDATION (CONSENT AGENDA/VOTING ITEM)

PRESIDENTIAL REPORT (INFORMATION ONLY)

## I. POLICY STATEMENT

Northern Kentucky University (NKU) 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 Northern Kentucky University institutional policy applies to all researchers/investigators submitting a grant through the Office of Research, Grants, and Contracts at Northern Kentucky University (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 Subpart F and 45 CFR Part 94](#). This policy also implements federal requirements contained in the [National Science Foundation’s \(NSF\) investigator financial disclosure policy](#).

## IV. DEFINITIONS

Among the definitions listed at [42 CFR 50.603](#) are several key definitions that must be known in order to understand the Financial Conflict of Interest (FCOI) regulation: Institution, Institutional Responsibilities, Investigator, Financial Interest, Financial Conflict of Interest (FCOI), Manage, and Significant Financial Interest (SFI).

**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/National Science Foundation (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, including 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 follows:

- 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 or 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 disclosed 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 a 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's research policy and procedures to maintain research 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 do the following:

- Have an active Financial Conflict of Interest Disclosure form on file.
- Update the Financial Conflict of Interest Disclosure form annually, and as the Investigator and/or the Investigator's dependents financial situation changes.
- 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. 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 their 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 will 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 “[Responsibility of Applicants for Promoting Objectivity in Research for which Public Health Service \(PHS\) Funding is Sought and Responsible Prospective Contractors](#)” promulgated by the U.S. Public Health Service: 42 CFR Part 50 and 45 CFR Part 94 -

National Institutes of Health (NIH) “[Financial Conflicts of Interest](#)” policy:

[National Science Foundation’s \(NSF\) investigator financial disclosure policy](#)

### REVISION HISTORY

REVISION TYPE	MONTH/YEAR APPROVED
Minor Revisions to secs. IV(B), VI, & VII + Editing	May 14, 2023
Revision	February 19, 2020
New Policy	May 4, 2017

# FINANCIAL CONFLICT OF INTEREST DISCLOSURE FOR RESEARCH

## PRESIDENTIAL APPROVAL

### PRESIDENT

Signature

*A. K. Vaidya*

Date *2/19/2020*

Ashish K. Vaidya

## BOARD OF REGENTS APPROVAL

### BOARD OF REGENTS (IF FORWARDED BY PRESIDENT)

- This policy was forwarded to the Board of Regents on the **Presidential Report (information only)**.  
Date of Board of Regents meeting at which this policy was reported: 03 / 18 / 2020.
- This policy was forwarded to the Board of Regents as a **Presidential Recommendation (consent agenda/voting item)**.
- The Board of Regents approved this policy on \_\_\_\_/\_\_\_\_/\_\_\_\_.  
(Attach a copy of Board of Regents meeting minutes showing approval of policy.)
- The Board of Regents rejected this policy on \_\_\_\_/\_\_\_\_/\_\_\_\_.  
(Attach a copy of Board of Regents meeting minutes showing rejection of policy.)

### VICE PRESIDENT & CHIEF STRATEGY OFFICER

Signature

*Bonita Brown*

Date *04/14/2020*

Bonita J. Brown