

NORTHERN KENTUCKY UNIVERSITY

***CONFLICT OF
INTEREST/FINANCIAL DISCLOSURE***

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Introduction

Northern Kentucky University encourages interaction with both the public and private sectors as an important component of all education, public-service activities, and research. Accordingly, Northern Kentucky University is committed to conducting its sponsored projects within the highest standards of integrity. This includes the identification of potential for conflicts of interest, and further, ensuring that the significant financial interest of an individual investigator does not compromise the objectivity of his/her funded research or educational activity.

Federal agencies have revised their grants administration policies to require that all grant applicants adopt, and enforce, written policies regarding conflicts of interest. These new requirements include a Financial Disclosure Statement which must be completed by the appropriate investigator and forwarded for review by the University.

Purpose

Public trust in the University's sponsored research and educational activities must remain high. The University has no interest in setting forth detailed policies and procedures that might interfere with employees' legitimate outside interest; rather, its desire is to protect the credibility of the University as well as its investigators. The University has a clear responsibility to identify, manage, reduce, and/or eliminate all potential conflicts of interest. It is the purpose of this policy to define conflicts of interest, identify those individuals who must report possible conflicts of interest, clarify the potential for such conflicts, and delineate the proper procedures for reviewing and addressing all potential conflicts of interest.

These policies apply only to research and educational activity projects sponsored by agencies with conflict of interest/financial disclosure policies.

Definitions

The terms used in this policy statement are defined as follows:

- A. University - Northern Kentucky University
- B. Conflict of Interest - Situations in which financial or other personal considerations may compromise, or have the appearance of compromising, an investigator's professional judgment in conducting and/or reporting research. Conflict occurs when an investigator's professional decisions are determined by considerations of financial gain for themselves or their immediate family or give improper advantage to an associated entity.

C. Associated Entity - Any trust, organization, or enterprise (other than the University) over which the investigator, or any member of the immediate family, exercises a controlling interest.

D. Significant financial Interest - Anything of monetary value, including, but not limited to:

- Salary or other payments for services (e.g., consulting fees or honoraria)
- Equity interest (e.g., stocks, stock options or other ownership interest)
- Intellectual property rights (e.g., patents, copyrights or royalties from such rights)

This term does not include:

- Salary, royalties or other remuneration from the University.
- Income from seminars, lectures or teaching engagements sponsored by public or non-profit entities.
- Income from service on advisory committees or review panels for public or non-profit entities.

E. Investigator - Principal investigator/project director, co-principal investigator, or any other person at the University who is responsible for the design, conduct, or reporting of research or educational activities funded, or proposed for funding, by any external sponsor.

F. Immediate Family - Investigator's spouse, dependent children, and other related persons living in the same household.

G. Negative Disclosure - Refers to financial Disclosure Forms (Attachment B) which, after review, indicate no potential financial conflict on the part of the investigator completing the form.

H. Positive Disclosure - Refers to Financial Disclosure Forms (Attachment B) which, after review, indicate there is either enough evidence, or enough doubt, to require further review by a University Conflict-of-interest Review Committee (CIRC).

I. Office of Record - The University office designated to maintain files, actions, and records pertaining to Financial Disclosure Forms completed by an investigator. Records, including the disclosure form and any subsequent actions taken to resolve conflicts of interest, must be kept on file for three years following termination of a sponsored award, or until the resolution of any government actions involving those records, whichever is longer.

J. Conflict-of-interest Review Committee (CIRC) - Standing University-wide committee appointed by the President or his/her designee and consisting of the University Legal Counsel (who shall serve as the Chair), the Director of Research, Grants and Contracts, three faculty members recommended by the Faculty Senate, and two persons recommended by Staff Congress. Their charge will be to review all positive conflicts of interest.

K. Confidentiality of Records - To the extent permitted by law, all records of financial interest submitted by an investigator are to be maintained in the respective Office of Record with the very highest level of security and strictest confidentiality.

L. Memorandum of Understanding (MOU) - A document developed and agreed to by an investigator and the CIRC which would constitute a plan for the resolution of an identified conflict or potential conflict of interest.

Disclosure and Review

In those instance where the University is engaged in, or intends to engage in, a sponsored project, a conflict of interest may occur if the investigator's affiliation with the external organization specifically meets any of the following criteria:

A. The investigator is an officer, director, partner, trustee, employee, advisory board member, or agent of an external organization funding a sponsored project in which the investigator is participating in any capacity.

B. The investigator is the actual or beneficial owner of more than 5 percent of the voting stock or controlling interest of such external organization, or has an equity interest that exceeds \$10,000.00 in value, as determined through reference to public prices or other reasonable measures of fair market value.

C. The investigator derives income of more than \$1 0,000 per year from an organization.

D. The investigator's immediate family meets any of the criteria stated in A through C above, either individually or as aggregated for the investigator and his/her immediate family.

It should be noted that it is the responsibility of those faculty/staff members of Northern Kentucky University, either full or part-time, who will be participating in a sponsored project covered by this policy, to initiate the disclosure process at the time of proposal submission indicating whether or not they have external affiliations which could constitute a conflict by virtue of failing into the criteria stated in paragraphs A-D above.

The Financial Disclosure Form must be completed at the time of submission and the review process, and resolution of conflicts, if any, must be completed prior to the University's expenditure of any funds under the award. The Financial Disclosure form (Attachment A) must be completed and forwarded to the investigator's immediate supervisor in order to initiate the review process. The disclosure form will be reviewed by the immediate supervisor for purposes of distinguishing between Negative- Disclosure - disclosure that reveals no financial conflict - and Positive- Disclosure - disclosure that requires additional review.

In those instances where the investigator's immediate supervisor concludes that the disclosure form clearly represents a Negative Disclosure, the supervisor will forward the form to the next-level supervisor for concurrence. If the next-level supervisor agrees that there is no conflict, that particular supervisors office so advises the investigator in writing and forwards the form to the Office of Research, Grants & Contracts, the official OFFICE OF RECORD for Negative Disclosure Forms. In those cases, the investigator may proceed without further review.

In those instances where the investigator's immediate supervisor or the next- level supervisor concludes that the disclosure form represents a Positive Disclosure, or if there is the slightest doubt, that supervisor will advise the investigator, in writing, and will forward the form directly to the Chair of the CIRC, who will convene the CIRC. A majority of members of the Committee must be present in order to review a disclosure form. The Chair will vote only in the case of ties.

In reviewing Positive Disclosure, the CIRC will be directed by the following practices and apply them as necessary:

A. Assure adherence to all relevant governmental and University policies.

B. Consider the nature and extent of the financial interest in the relationship between the investigator and the sponsoring organization.

C. Obtain additional information from the investigator as may be necessary in resolving conflicts.

D. Act within ten (10) working days so as not to unduly delay the conduct of the sponsored project.

In the final analysis, the CIRC may take any one of the following actions:

A. Approve the Financial Disclosure Form as revealing no financial conflict of interest, thereby, allowing for the acceptance of the respective sponsored-project award.

B. Approve the Financial Disclosure Form subject to modifications.

C. Disapprove the Financial Disclosure Form as revealing an unresolvable financial conflict to interest, thereby negating the submission or acceptance of the sponsored-project award. Once any of the above- mentioned options are exercised, the Chair of the CIRC will advise the investigator in writing, and that office will officially become the OFFICE OF RECORD for all reviewed Positive Disclosure Forms.

If an investigator's financial situation changes, in terms of new financial interest, after the submission of a financial disclosure form, it is the responsibility of that investigator to update his/her situation by immediately submitting another Financial Disclosure Form showing these financial changes. In the case of multi-year funding, a review of an investigator's situation must take place at least, annually.

Appeals Process

If the investigator is dissatisfied with the action of the CIRC, that individual may, within five (5) working days, appeal in writing directly to the President. The President will confer with the investigator, as well as the CIRC, to the extent necessary and respond, in writing, to the investigator with a decision within ten (10) working days. The decision of the President is final.

Violations of Policy

Any violations of this policy, such as willful concealment of financial interest by an investigator, may result in sanctions being imposed upon the violating individuals. These sanctions will preclude faculty/staff from receiving external funding for at least one year, but not more than five years. The CIRC will review any alleged violations brought to its attention. That committee will make written recommendations to the President prior to the imposition of any sanctions. The decision regarding sanctions will be that of the President and will be in keeping with The Faculty Handbook & Personnel Policy & Procedure Manual. The decision of the President is final. It should also be noted that if the failure of an investigator to comply with the policy of the University has directly biased the design, conduct, or reporting of the externally funded research, or educational activity the University must promptly notify the external agency of the corrective action taken. That will be the responsibility of the Chair of the CIRC.

Sponsor Requirements

Some sponsors, particularly governmental agencies, may have requirements that differ from this policy with regard to the timing and/or frequency of disclosures and other provision as well. When differences occur, the sponsor's requirements shall prevail.

The CIRC will arrange to keep the relevant agency informed if the institution finds that it is unable to satisfactorily manage an actual, or potential, conflict of interest situation.

The term does not include:

1. salary, royalties, or other remuneration from institution;
2. income from seminars, lectures, or teaching engagements sponsored by public or nonprofit entities@
3. income from service on advisory committees or review panels for public or nonprofit entities; or

Disclosure Procedures:

- (1) All investigators must disclose their significant financial interests utilizing the form which follows and attaching all required supporting documentation. The completed form and packet must be submitted with the proposal and the Internal Review and Approval Form through the University channels. Supporting documentation should be submitted in a sealed envelope marked confidential.
- (2) In accordance with Federal regulations, a complete disclosure must be made by investigator(s) prior to submission of the proposal.
- (3) Resolutions to conflicts of interest will be incorporated in a Memorandum of understanding (MOU) that is executed between the Investigator(s) and the University Conflict of Interest Review Committee prior to award acceptance.