



#### 4.4.1P

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Chapter 4, Academic Research and Sponsored Projects

Section 1, Conflict of Interest and Financial Disclosure

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Responsible Executive: Provost/Vice President for Academic Affairs

Responsible Office(s): Graduate Education and Research, Sponsored Programs

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## Conflict of Interest and Financial Disclosure

### Policy Statement

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

#### 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 interests; 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 conflicts of interest and/or conflicting financial interest. 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.

### Entities Affected by the Policy

- Any faculty, student, or staff engaged in sponsored research or educational activities

### Policy Background

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

## Policy Procedures

### **Determination of Conflict of Interest**

In those instances 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 specifically meets any of the following criteria:

- The investigator is an officer, director, partner, trustee, employee, advisory board member, or agent of the sponsor funding a project in which the investigator is participating in any capacity.
- The investigator has an equity interest that, when aggregated, is both more than \$10,000 and is more than a 5 percent ownership interest in any single entity.
- The investigator derives income or other payments that, when aggregated for the next 12 months, is expected to be more than \$10,000.
- The investigator's immediate family meets any of the criteria stated above.

It should be noted that it is the responsibility of those faculty/staff members of Eastern 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 of interest by virtue of falling into the criteria stated above.

### **Financial Disclosure Form and Internal Review Form**

The Financial Disclosure Form must be completed and forwarded with the proposal and Internal Review Form in order to initiate the review process. The Financial Disclosure Form will be reviewed by the immediate supervisor, the next-level supervisor, and the Director of Sponsored Programs for purposes of distinguishing between Negative Disclosure (disclosure that reveals no financial conflict) and Positive Disclosure (disclosure that requires additional review).

### **Negative Disclosure**

In those instances where the investigator's Financial Disclosure Form clearly represents a Negative Disclosure, the Negative Disclosure Form will be filed in the Office of Record.

### **Positive Disclosure**

In those instances where it is concluded that the disclosure form does represent a Positive Disclosure, or if there is the slightest doubt, the Director of Sponsored Programs will advise, in writing, the investigator and the investigator's immediate and next-level supervisor. The Director of Sponsored Programs, who is also the Chair of the CIRC, will convene a meeting of the CIRC for purposes of reviewing the Positive Disclosure.

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

- Assure adherence to all relevant governmental and University policies.
- Consider the nature, and extent, of the financial interest in the relationship between the investigator and the external sponsor.
- Obtain additional information from the investigator as may be necessary in resolving conflicts.

Act within ten (10) working days so as not to unduly delay the process.

**Actions by the CIRC**

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

1. Approve the Financial Disclosure Form.
2. Approve the Financial Disclosure Form subject to modifications that might be imposed to manage, reduce, or eliminate conflicts of interest.

Disapprove the Financial Disclosure Form as revealing an un-resolvable conflict of interest. Once any of the above-mentioned options are exercised, the Chair of the CIRC will advise the investigator and the funding agency, in writing.

**Conditions**

In the case of multi-year funding, a review of an investigator's situation must take place, annually.

**Changes that May Affect Original Disclosure**

If an investigator's financial situation changes in terms of new reportable Significant Financial Interests, after the submission of a Financial Disclosure Form, it is the responsibility of that investigator to update his/her situation by immediately submitting to the Director of Sponsored Programs, via the immediate supervisor and the next-level supervisor, another Financial Disclosure Form showing the financial changes.

**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 provisions as well. When differences occur, the sponsor's requirements shall prevail.

**Notification of Sponsor**

The Chair of the CIRC will advise the relevant funding sponsor if the institution finds that it is unable to satisfactorily manage, reduce, or eliminate a conflict of interest situation.

## Definitions

<b>Associated Entity</b>	Any trust, organization, or enterprise (other than the University) over which the investigator, or any member of the immediate family, exercises a controlling interest.
<b>Confidentiality of Records</b>	To the extent permitted by law, all records of financial interest submitted by an investigator will be on file in the Office of Record and will be accorded the very highest level of security and strictest confidentiality.
<b>Conflict of Interest</b>	A conflict of interest exists if the reviewer(s) of disclosures determine(s) that a Significant Financial Interest "could directly and significantly affect the design, conduct, or reporting of research and/or educational activity projects." 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.
<b>Conflict-of-Interest Review Committee (CIRC)</b>	The CIRC will be a subcommittee of faculty from the University's standing Committee on Research. Said subcommittee will be appointed by the Dean of Graduate Education and Research. The Chair of the

CIRC shall be the Director of Sponsored Programs. The University Counsel shall serve as a continuing member of the CIRC. The committee's charge will be to review all positive conflicts of interest situations for the purpose of managing, reducing, or elimination potential conflicts of interest.

A majority of the CIRC will constitute a quorum. The Chair of the CIRC will vote only in the case of a tie.

<b>Immediate Family</b>	Principal investigator's/project director's spouse, co-principal investigator's/co-project director's spouse, and/or dependent children.
<b>Investigator</b>	Principal investigator/project director, co-principal investigator/ co-project director, or any other person, including sub grantees or subcontractors, responsible for the design, conduct, or reporting on research or educational activities funded by any external sponsor.
<b>Memorandum of Understanding (MOU)</b>	A document developed and agreed to by an investigator and the CIRC, which would constitute a plan for the resolution of an identified conflict of interest.
<b>Negative Disclosure</b>	Refers to Financial Disclosure Form (Attachment B), which, after review, indicates no conflict of interest on the part of the investigator.
<b>Office of Record</b>	The University office designated to maintain files, actions, and records pertaining to Financial Disclosure Forms completed by an investigator. Records, including the Financial Disclosure Form and any subsequent actions taken to resolve conflicts of interest, must be kept on file for three (3) years from the date of submission of the final expenditure report of any government actions involving those records, whichever is longer. The Division of Sponsored Programs will be the University Office of Records.
<b>Positive Disclosure</b>	Refers to Financial Disclosure Form which, after review, indicates there is either enough evidence, or enough doubt, to require further review by a University Conflict of Interest Review Committee (CIRC).
<b>Significant Financial Interest</b>	<p>Anything of monetary value, including, but not limited to:</p> <ul style="list-style-type: none"> <li>• Salary or other payments for services (e.g., consulting fees/honoraria);</li> <li>• Equity interests (e.g., stocks, stock options or other ownership interests);</li> <li>• Intellectual property rights (e.g., patents, copyrights, and royalties from such rights).</li> </ul> <p>This term does not include:</p> <ul style="list-style-type: none"> <li>• Salary, royalties or other remuneration from the institution;</li> <li>• Income from seminars, lectures, or teaching engagements sponsored by public or nonprofit entities;</li> <li>• Income from service on advisory committees or review panels for public or nonprofit entities;</li> <li>• An equity interest that, when aggregated for the investigator and the investigator's immediate family, meets both of the following tests: does not exceed \$10,000 in value as determined through reference to public prices or other reasonable measures of fair market value, and does not represent more than a 5 percent ownership interest in any single entity; or</li> <li>• Salary, royalties, or other payments that, when aggregated for the investigator and the investigator's immediate family, are not expected to exceed \$10,000 during the next 12-month period.</li> </ul>
<b>University</b>	Eastern Kentucky University

## Violations of the 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 individual(s). The CIRC will review any alleged violations brought to its attention. That Committee will make written recommendations to the Dean of Graduate Education and Research, who will confer with the Provost/Vice President for Academic Affairs prior to the imposition of any sanctions. The ultimate decision regarding sanctions to be imposed will be that of the Provost/Vice-President of Academic Affairs and will be in keeping with the Eastern Kentucky University policies. The decision by the Provost/Vice President may be appealed to the President.

If the failure of an investigator to comply with the conflict of interest policy of the University has directly biased the design, conduct, or reporting of the externally funded research, or educational activity, the University will promptly notify the external sponsor of the corrective action taken. This notification process will be the responsibility of the Chair of the CIRC.

## Interpreting Authority

Vice President of Research and Dean of Graduate Education

## Policy Adoption Review and Approval

### Policy Revisions

<u>Date</u>	<u>Entity</u>	<u>Action</u>
November 2001	Unknown	Revision

### Policy Issued

<u>Date</u>	<u>Entity</u>	<u>Action</u>
<b>October 28, 1995</b>	<b>Board of Regents</b>	<b>Adopted</b>
September 11, 1995	President Hanley Funderburk	Approved
May 1, 1995	Faculty Senate	Approved