EXECUTIVE AND ACADEMIC AFFAIRS COMMITTEE

Conflict of Interest Policy

Federal regulations mandate that institutions which receive grants and contracts should have a conflict of interest policy in place applicable to the people involved. I recommend approval by the Board of Regents.
TO: Mr. Giles Black, University Counsel
FROM: Donna M. Masters, Director
SUBJECT: Conflict of Interest Policy
DATE: September 8, 1995

I have made the change you asked that I make and, as you requested, am returning the policy to you for subsequent approval. As soon as it has the President’s approval, this office would be pleased to make on-campus distribution.

As always, thank you for your assistance.

Enclosures

cc: Vice President Enzie
    Dean Falkenberg
Introduction

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.

Federal agencies have revised their grants' administration policies to require that 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.

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 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.

These policies apply to all sponsored research and educational activity projects.

Definitions

The terms used in this policy statement are defined as follows:
A. University - Eastern Kentucky University

B. Conflict of Interest - A conflict of interest exists if the reviewer(s) of disclosures determine 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.

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/honoraria);
- Equity interests (e.g., stocks, stock options or other ownership interests);
- Intellectual property rights (e.g., patents, copyrights, and royalties from such rights).

This term does not include:

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

E. Investigator - Principal investigator/project director, co-principal investigator/co-project director, or any other person, including subgrantees or subcontractors, responsible for the design, conduct, or reporting of research or educational activities funded by any external sponsor.

F. Immediate Family - Principal investigator's/project director's spouse, co-principal investigator's/co-project director's spouse, and/or dependent children.

G. Negative Disclosure - Refers to Financial Disclosure Form (Attachment B) which, after review, indicates no conflict of interest on the part of the investigator.

H. Positive Disclosure - Refers to Financial Disclosure Form (Attachment B) 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).

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 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 a sponsored award, or until the resolution of any government actions involving those records, whichever is longer. The Division of Grants and Contracts will be the University Office of Record.

J. Conflict-of-Interest Review Committee (CIRC) - The Conflict-of-Interest Review Committee (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 Studies and Research. The Chair of the Conflict-of-Interest Review Committee shall be the Director of Grants and Contracts. 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 eliminating 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.

K. Confidentiality of Records - 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.

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 of interest.

Disclosure and Review

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:

A. 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.

B. 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.

C. The investigator derives income or other payments that, when aggregated for the next 12 months, is expected to be more than $10,000.

D. The investigator’s immediate family meets any of the criteria stated in A-C 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 in paragraphs A-D above.
The Financial Disclosure Form (Attachment A) 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 Grants and Contracts 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 Financial Disclosure Form clearly represents a Negative Disclosure, the Negative Disclosure Form will be filed in the Office of Record.

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 Grants and Contracts will advise, in writing, the investigator and the investigator’s immediate and next-level supervisor. The Director of Grants and Contracts, 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:

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 external sponsor.

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 process.

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

A. Approve the Financial Disclosure Form.

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

C. Disapprove the Financial Disclosure Form as revealing an unresolvable 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.
agency, in writing.

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 Grants and Contracts, via the immediate supervisor and the next-level supervisor, another Financial Disclosure Form showing the financial changes. In the case of multi-year funding, a review of an investigator's situation must take place, annually.

Appeals Process

If the investigator is dissatisfied with the conclusion of the CIRC, that individual may, within five (5) working days, appeal in writing directly to the Dean of Graduate Studies and Research. The Dean 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 Dean of Graduate Studies and Research may be appealed through the appropriate University channels.

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

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.

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.
Attachment A

EASTERN KENTUCKY UNIVERSITY

FINANCIAL DISCLOSURE SUMMARY INFORMATION
(Applicable to all Sponsored Project Proposals)
(Effective 10/1/95)

What is required?

Federal regulations require institutions to have policies and procedures in place that ensure that investigators disclose any conflicts of interest that may reasonably appear to affect the objectivity of his/her funded research or educational activity. Such disclosures must be made prior to the submission of a proposal for funding, and institutions must develop specific mechanisms by which conflicts of interest will be satisfactorily managed, reduced, or eliminated prior to expenditure of funds of an award.

*If new reportable Significant Financial Interests are obtained at any time during the period after the submission of the proposal through the period of the award, the filing of an updated Financial Disclosure Form is also required. In cases of multi-year funding, a review of investigator's situation must take place annually.

Who is covered?

"Investigator" means the principal investigator/project director, co-principal investigator/co-project director, and any other person, including subgrantee or subcontractor, responsible for the design, conduct, or reporting of research or educational activities funded by an external sponsor. In this context, the term "Investigator" includes the Investigator's immediate family.

What must be disclosed?

Each investigator shall disclose all significant financial interests:

(i) that would reasonably appear to be affected by the research or educational activities funded by an external sponsor; or

(ii) in entities whose financial interests would reasonably appear to be affected by such activities.
What is covered?

"Significant Financial Interests" means 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 interests); and intellectual property rights (e.g., patents, copyrights, and royalties from such rights). The term does not include:

(1) salary, royalties, or other remuneration from the 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;

(4) 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

(5) Salary, royalties, or other payments, when aggregated for the investigator and the investigator's immediate family, are not expected to exceed $10,000 during the 12-month period.

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. Any supporting documentation should be submitted in a sealed envelope marked confidential.

(2) In accordance with Federal regulations, disclosure must be made by investigator(s) prior to the submission of the proposal to the external sponsor.

(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 expenditure of funds of an award.
Attachment B

EASTERN KENTUCKY UNIVERSITY

INVESTIGATOR(S) FINANCIAL DISCLOSURE FORM
(Applicable to all Sponsored Project Proposals)
(Effective 10/1/95)

Investigator(s) Name ________________________________

Department/Unit __________________________________

College/Unit ______________________________________

Proposal Submitted to ________________________________

Project Period ______________________________________

Certification: I have read and understand the University's Policy on Conflict-of-Interest/Financial Disclosure and affirm that the information below is true to the best of my knowledge.

1. Are you or any member of your immediate family an officer, director, partner, trustee, employee, advisory board member, or agent of the external sponsor funding this project or of any organization from which goods and services will be obtained under the sponsored project?

   Yes (If so, describe in detail on an attached sheet the nature and extent of the affiliation.)

   No

2. Do you or any immediate family member have an equity interest that, when aggregated for the investigator and the investigator's immediate family, meets both of the following tests: exceeds $10,000 in value as determined through reference to public prices or other reasonable measures of fair market value, and represents more than a 5 percent ownership interest in any single entity?

   Yes (if so, describe in detail on an attached sheet the nature and extent of the equity interest.)

   No
3. Do you or any member of your immediate family anticipate receiving salary, royalties or other payments that, when aggregated for the investigator and investigator's immediate family, are expected to exceed $10,000 during the next 12-month period.

   ___ Yes (If so, describe on an attached page the amount of the income and the reason for which it was or will be derived.)

   ___ No

4. Do you have any affiliation with the external sponsor funding this sponsored project that would affect, or be perceived to affect, the results of the research or educational activities in any manner?

   ___ Yes (If so, describe on an attached page the nature of the affiliation and the amount of time per week you dedicate to it.)

   ___ No

Further I agree, if required:

- To update this disclosure during the period of the award, either on an annual basis, or as new reportable significant financial interests are obtained.

- To cooperate in the development of a Memorandum of Understanding (MOU) that constitutes a conflict of interest "resolution plan."

- To comply with any conditions or restrictions imposed by the University to manage, reduce, or eliminate conflicts of interest or forfeit the award.

Signature of Faculty Member: (Original signature only - a "per" signature is not acceptable).
Endorsements:

I have reviewed the Investigator Financial Disclosure Form and have determined that it is a Negative Disclosure revealing no conflict of interest on the part of the investigator.

I have reviewed the Investigator Financial Disclosure Form as a Positive Disclosure in need of further review and for the possible development of a Memorandum of Understanding (MOU) with the investigator.

Department/Unit Head: ________________________________ Signed __________________________ Date

College Dean/Unit Head: ________________________________ Signed __________________________ Date

I concur that this is a Negative Disclosure.

I concur that this is a Positive Disclosure in need of further review and of a meeting of the CIRC for resolution and/or the development of a Memorandum of Understanding (MOU).

Director, Grants/Contracts: ____________________________ Signed __________________________ Date
EASTERN KENTUCKY UNIVERSITY
MANAGING CONFLICTS OF INTEREST*

Although not all-inclusive, some examples of conditions or restrictions which might be imposed to manage, reduce, or eliminate conflicts of interest are as follows:

A. Public disclosure of significant financial interests.

B. Monitoring of research/educational activity by independent reviewers.

C. Modification of the research/educational activity.

D. Disqualification from participation in all or that portion of sponsored projects that would be affected by significant financial interests.

E. Divestiture of significant financial interests.

F. Severance of relationships that create conflicts of interest.

*If the reviewer(s) determines that imposing conditions or restrictions would be either ineffective or inequitable, and that the potential negative impacts that may arise from a significant financial interest are outweighed by interests of scientific progress, technology transfer, or the public health and welfare, then the reviewer(s), if allowed by the external sponsor, may allow the research and/or educational activity to go forward without imposing such conditions or restrictions.
The Ad Hoc Committee on Alternative Schedules for Classes and Holidays: Dr. Foster

Dr. Karen Foster reported that Committee was presently working on determining the feasibility of a number of options. Once the feasibility of options has been determined, the committee will gather input from the University community. If specific motions are supported, the Committee will present them by the end of the 1995 fall semester.

Editorial Advisory Committee #1: Senator Creek

Senator Creek reported that the Committee had completed all but one item of its charge. During this year the committee brought before the Senate guidelines for a Faculty Senate newsletter. By fall, the committee will select and bring before the Senate a logo to be used on official documents of the Senate.

Editorial Advisory Committee #2: Senator Creek

The committee met on April 28, and elected Libby Fraas chair. They decided that the position of editor should be advertised in the Faculty Bulletin, FYI, and Eastern Progress. The deadline for receiving applications will be August 28, 1995. The Committee hopes to have the first newsletter mailed with the Senate’s September minutes.

Ad Hoc Committee on Child Care: Senator Kopacz

Senator Kopacz reported that the Committee had finished its research. It conducted a survey of faculty and staff child-care needs in spring 1994; it met with representatives from a national chain of workplace-specific child-care centers; it surveyed market area child-care providers to determine the extent to which they were filled to capacity, and got information on their fees; it generated several operational budgets; it met with Associate Vice-President Marijo LeVan to brainstorm about possible sites; and finally, it met with James Street, Director of the Physical Plant, to discuss renovation costs.

The final report is in the drafting stage. The Committee plans to work on it over the summer and return its final report to the Senate at its September meeting.

Motion to Approve Policy on Conflict of Interest/Financial Disclosure: Senator Falkenberg

Senator Falkenberg moved approval of the policy on conflict of interest/financial disclosure. (See attached document.) She explained that federal regulations require any institution receiving federal research funds to have such a policy related to its research. Donna Masters, Director of Grants and Contracts, worked with Senator Falkenberg drawing up the proposed EKU policy using federal standards. After general discussion, the motion was approved.