



# Eastern Kentucky University

## Policy and Regulation Library

Academic Regulation: 4.4.1ACR

Responsible Office(s): Office of Research and  
Division of Sponsored Programs

Effective: October 28, 1995

Next Review Date:

## Academic Regulation: 4.4.1ACR Conflicts of Interest

### Statement

Eastern Kentucky University encourages interaction with both the public and private sectors as an important component of all education, public service, and research activities. Accordingly, the University is committed to conducting its sponsored projects with the highest standards of integrity. This includes the identification of the potential for conflicts of interest and further ensuring that any conflicting financial interests of an individual investigator do 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. It is the purpose of this Policy to define conflicts of interest, identify those individuals who must report interests, clarify the potential for conflicts, and outline procedures for reviewing potential conflicts and managing identified conflicts.

### Entities Affected

Any faculty, staff, or student engaged in sponsored projects

### Procedures

#### **Disclosure of Relationships with Sponsoring Agencies and Vendors**

In those instances where the University is engaged in, or intends to engage in, an externally-sponsored project, a conflict of interest may occur if the project director's or co-project director's affiliation with the agency sponsoring the project or with vendors from which goods or services will be procured meets any of the following

criteria:

- The project director or co-project director or any member of the project director's or co-project director's immediate family 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 project director or co-project director has an equity interest in the external sponsor that, when aggregated for the project director or co-project director and the project director's or co-project director's immediate family, meets both of the following tests: (1) exceeds \$5,000 in value as determined through reference to public prices or other reasonable measures of the fair market value; and (2) represents more than a 5% ownership interest in any single entity.
- The project director or co-project director anticipates receiving salary, royalties, or other payments from the external sponsor that, when aggregated for the project director or co-project director and the project director's or co-project director's immediate family, are expected to exceed \$5,000 during the next twelve months.
- The project director or co-project director or any member of the project director's or co-project director's immediate family has an affiliation with the external sponsor that would affect, or be perceived to affect, the results of the research or educational activities in any manner.
- The project director or co-project director or any member of the project director's or co-project director's immediate family is an officer, director, partner, trustee, employee, advisory board member, or agent of any organization from which goods or services will be procured through the sponsored project.

The Internal Review and Approval Form (IRAF) requires that project directors and co-project directors disclose any relationships that meet the above criteria as part of the internal review process for each proposal submission.

This information shall be reviewed by the immediate supervisor, the next-level supervisor, the Director of Sponsored Programs, and the Institutional Official for the purpose of determining whether a potential conflict of interest may exist that requires additional review.

### **Disclosure of Significant Financial Interests**

In addition to potential conflicts of interest with sponsoring agencies and/or vendors, some sponsoring agencies require the disclosure of Significant Financial Interests and a determination by the Institutional Official regarding whether the interests are related to the proposed project. The requirements in this section apply to investigators on projects proposed to or funded by agencies with such requirements, including all agencies operating under Public Health Services (PHS).

A financial conflict of interest exists when an investigator's Significant Financial Interests could directly and significantly affect the design, conduct, or reporting of research or

educational activities. A Significant Financial Interest is related to the project when it could be affected by the project or is in an entity whose financial interest could be affected by the project.

A Significant Financial Interest involves one or more of the following interests of an investigator or the investigator's spouse and dependent children that reasonably appears to be related to the investigator's institutional responsibilities:

- 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 for the investigator and the investigator's immediate family, 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
- 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)
- Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests

Investigators also must disclose the occurrence of reimbursed travel (travel expenses paid by investigator and reimbursed by outside entity) or sponsored travel (travel expenses paid on behalf of the investigator rather than reimbursed to the investigator) related to their institutional responsibilities. Travel that is reimbursed or sponsored by a Federal, state, or local government agency, an institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education does not require disclosure. Disclosures for reimbursed or sponsored travel must include the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration. The Institutional Official will determine if further information is needed in order to evaluate whether the travel constitutes a conflict.

The definition of a Significant Financial Interest excludes the following types of financial interests:

- Salary, royalties, or other remuneration paid by the University to the investigator if the investigator is currently employed by the University, including intellectual property rights assigned to the University and agreements to share in royalties related to such rights
- 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; an academic teaching hospital; a medical center; or a research institute that is affiliated with an institution of higher education
- Income from service on advisory committees or review panels for a Federal, state, or local government agency; an Institution of higher education; an academic teaching hospital; a medical center; or a research institute that is affiliated with an institution of higher education

For proposals submitted to sponsoring agencies that require the disclosure of Significant Financial Interests, Sponsored Programs shall notify all involved investigators of pre-submission requirements and provide links to this Policy, the sponsoring agency's Conflict of Interest policy, and training information. Access to a secure online disclosure report will also be provided with instructions for submission. The disclosure shall be reviewed by the Director of Sponsored Programs and the Institutional Official for the purpose of determining whether a potential conflict of interest may exist that requires additional review.

In the event that a proposal is not determined to be subject to additional requirements, the additional requirements will be enforced upon receipt of an award if determined to be applicable. In such cases, the additional compliance requirements must be satisfied prior to expenses being incurred on an award.

For sponsored projects that require the disclosure of Significant Financial Interests, investigators are also responsible for reporting on an annual basis and within 30 days of any changes, including the disclosure of any newly obtained reportable interests.

### **Financial Conflicts of Interest Training**

The University provides access to comprehensive training on financial conflicts of interest through the Collaborative Institutional Training Initiative (CITI). This training is encouraged for all faculty, staff, and students involved in sponsored projects and is required for all investigators on research proposed for funding from PHS agencies. Training may also be required by other agencies. When training is required, it must be completed prior to any investigator engaging in the sponsored project and must be repeated at least every four years. In addition, investigators on PHS-supported research shall be required to complete immediate training when policy changes affect investigator requirements, when new to the institution, and when not in compliance with this Policy or a conflict of interest management plan.

### **Conflict of Interest Review Committee (CIRC)**

The Conflict of Interest Review Committee (CIRC) shall include a subcommittee of faculty from the University's standing University Research Committee. This subcommittee shall be appointed by the Institutional Official. The Chair of the CIRC shall be the Director of Sponsored Programs. University Counsel shall also serve as a continuing member of the CIRC. The committee's charge shall be to review disclosures that represent potential conflicts of interest for the purpose of determining whether

conflicts exist and to advise in managing, reducing, or eliminating identified conflicts. A majority of the CIRC shall constitute a quorum. The Chair of the CIRC shall vote only in the case of a tie.

### **Determination of No Conflict**

In those instances where an individual's disclosures clearly do not represent a conflict of interest following review by the Director of Sponsored Programs and Institutional Official, the disclosures shall be filed in the Office of Record with no additional action required.

### **Determination of Potential Conflict**

In those instances where it is concluded that a disclosure represents a potential conflict of interest, the Director of Sponsored Programs shall 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, shall convene a meeting of the CIRC for purposes of reviewing the disclosure and determining whether a conflict exists.

In reviewing the potential conflict of interest, the CIRC shall be guided by the following practices:

- Assure adherence to all relevant sponsoring agency and University policies and requirements
- Consider the nature and extent of the financial interest in the relationship between a project director or co-project director and the external sponsor and/or vendor
- Consider whether an investigator's Significant Financial Interests could directly and significantly affect the design, conduct, or reporting of research or educational activities
- Obtain additional information from the disclosing individuals as may be necessary in evaluating the potential conflict
- Act within ten (10) business days so as not to unduly delay the process

### **Actions by the CIRC**

The CIRC's determination shall reflect one of the following outcomes:

1. Determination that a conflict does not exist, in which case, no further action is necessary
2. Determination that a conflict exists that can be managed, in which case, a management plan shall be developed
3. Determination that a conflict exists that cannot be managed, in which case, the sponsored project proposal shall be withdrawn or the sponsored project award shall be terminated

Once the CIRC's determination has been finalized, the Chair of the CIRC shall advise the investigator in writing.

When the CIRC determines that a financial conflict of interest exists, a management plan shall be developed that specifies the actions that have been and will be taken to

manage the conflict. The management plan shall be drafted by the CIRC with input from the investigator and shall include the following details:

- Role and principal duties of the investigator in the sponsored project
- Conditions of the management plan
- Description of how the management plan is designed to safeguard objectivity in the project
- Confirmation of the investigator's agreement to the management plan
- Description of how the management plan will be monitored to ensure investigator compliance
- Other information as needed

Examples of conditions and restrictions that might be imposed to manage, reduce, or eliminate conflicts of interest include, but are not limited to, the following:

- public disclosure of Significant Financial Interests, including disclosure in publications and presentations
- disclosure of financial conflicts of interest directly to participants in research involving human subjects
- monitoring of research by independent reviewers
- modification of the research plan
- changes in personnel appointments or responsibilities
- disqualification of personnel from participation in all or a portion of the research that would be affected by Significant Financial Interests
- divestiture of Significant Financial Interests
- severance of relationships that create conflicts

If the CIRC determines that a conflict exists that cannot be managed, the Chair of the CIRC shall notify the sponsoring agency and request a proposal withdrawal or award termination in accordance with the agency's established procedures.

#### **Changes that May Affect Original Disclosure**

If a project director or co-project director's situation changes so that any response to the conflict of interest questions on the IRAF is no longer accurate, the project director or co-project shall submit an updated IRAF to Sponsored Programs so that the new information can be routed for internal review, including review by the immediate supervisor, the next-level supervisor, the Director of Sponsored Programs, and the Institutional Official.

If an investigator's financial situation changes in terms of new reportable Significant Financial Interests, the investigator shall submit a new Significant Financial Interests Report within 30 days.

#### **Sponsoring Agency Requirements**

Some sponsoring agencies may have requirements that differ from this Policy with regard to the timing and/or frequency of disclosures and other provisions. When differences occur, the agency's requirements shall be enforced in addition to the requirements outlined in this Policy.

### **Conflict of Interest Reporting to Sponsoring Agencies**

In all cases, the Chair of the CIRC shall advise the sponsoring agency if the institution finds that it is unable to satisfactorily manage, reduce, or eliminate a conflict of interest.

In addition, when required by a sponsoring agency's requirements, the Chair of the CIRC shall submit a Financial Conflict of Interest report for each identified conflict according to the agency's defined process that includes the following information:

- Name of investigator who has the conflict
- Name of entity with which the conflict exists
- Nature of the Significant Financial Interest
- Value of the financial interest
- Description of how the financial interest relates to the sponsored project and why the institution determined that the financial interest conflicts with the project
- Details of the institution's management plan
- Any additional information required by the agency

Reports on retrospective reviews shall also include the aforementioned data elements, along with the following:

- Reason for the retrospective review
- Detailed methodology used for the retrospective review, including methodology of the review process, composition of the review panel, and documents reviewed
- Findings and conclusions of the review

When required by a sponsoring agency, notification shall occur on the following timelines unless otherwise prescribed by the agency:

- Prior to the expenditure of funds for existing conflicts
- Within 60 days of new or newly identified conflicts
- Within 60 days of identifying conflicts for any new investigator added to a project
- Promptly following a retrospective review to update a previously submitted report
- At least annually throughout the project period

If bias is found in research, the Chair of the CIRC shall notify the sponsoring agency within 30 days through the submission of a mitigation report. The mitigation report shall include the elements documented in the retrospective review as well as a description of the impact of the bias on the project and the University's actions taken and/or planned to eliminate or mitigate the effect of the bias (i.e., impact on the project; extent of harm done, including any qualitative and quantitative data to support any actual or future harm; analysis of whether the project is salvageable).

### **Confidentiality and Maintenance of Records**

Recognizing that details about an investigator's financial interests is highly sensitive information, extra care will be taken to protect the confidentiality of disclosures of financial interests to the extent permitted by law. Submissions shall be stored in the

University's secure online routing system for sponsored projects and related compliance tasks. A copy of the investigator's submissions will be accessible through the investigator's account.

IRAF submissions are accessible by co-project directors, supervisors of project directors and co-project directors, budget unit heads contributing cost share to a project, Sponsored Programs staff, the Institutional Official, and the Associate Vice President for Financial Affairs or designee. They may also be accessed by other authorized individuals within the University as required for business purposes, including staff in the offices of Internal Audit, University Counsel, and Financial Affairs.

Access to Significant Financial Interests reports will be more restricted. The Institutional Official and designees in Sponsored Programs will have access to the digital records, which will not be printed for storage in hard copy in the Office of Record. These records may also be accessed by other authorized individuals within the University as required for business purposes, including staff in the offices of Internal Audit, University Counsel, and Financial Affairs.

In the event that a potential conflict of interest is identified, the investigator shall first be notified. To the extent necessary to review the potential conflict, information from disclosures will be shared with the investigator's first and second level supervisors, with members of the CIRC, and with the Executive Vice President for Academic Affairs/Provost. In the event of an appeal, information will also be shared with the President.

If an investigator is determined to have a financial conflict of interest, the conflict must be reported to the external sponsoring agency, and in most cases, made available publicly upon request, to human research subjects, and in the publication or presentation of results.

Records, including the initial and continuing disclosures and any subsequent actions taken to resolve conflicts of interest, shall be kept on file for three years from the date of submission of the final expenditure report or any government actions involving those records, whichever is longer. The Division of Sponsored Programs shall be the University's Office of Record.

#### **Public Accessibility of Policy and Conflicts of Interest**

This Policy shall be publicly accessible through the University's Policy website and through Sponsored Programs' website.

When required by sponsoring agencies, information about identified conflicts of interest shall be made available to the public within five calendar days of the receipt of a written request. The University's response to the public request shall include all data elements required by the sponsoring agency and reflect the most recent information available about the conflict. For PHS-funded research, data elements shall include the investigator's name, title, and role in the project; the name of the entity in which the



Significant Financial Interest is held; and the nature and value of the Significant Financial Interest. Details required for public disclosure shall remain available for a period of three years from the date on which the information was most recently updated.

### **Subrecipient Requirements**

Conditions of the University's awards shall be passed to subrecipients through the terms and conditions included in subawards. For PHS-funded subawards, a specific term shall be included that requires certification by the subrecipient to assume responsibility for both training and reporting requirements in accordance with PHS policy. The subaward term also requires that subrecipients report to the University any identified conflicts of interest that require disclosure so that the University can report the conflicts in accordance with the sponsoring agency's requirements. In the event that a subrecipient organization does not have an institutional policy that complies with the requirements of an award, the organization may elect to follow the University's policy and procedures if specifically authorized in the subaward terms. In situations where appropriate, the University may add a subaward term requiring that subrecipient investigator disclosures be submitted to the University for review, management, and reporting.

## Definitions

- **Associated Entity:** Any trust, organization, or enterprise (other than the University) in which the investigator, or any member of the immediate family, has a financial interest
- **Conflict of Interest:** Exists if the reviewers of disclosures determine that an investigator's interests could directly and significantly affect the design, conduct, or reporting of research and/or educational activities in sponsored 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.
- **Conflict of Interest Review Committee (CIRC):** A subcommittee of faculty from the University's standing University Research Committee appointed by the Institutional Official, as well as the Director of Sponsored Programs and University Counsel, charged with reviewing disclosures that represent potential conflicts of interest for the purpose of determining whether conflicts exist and advising in managing, reducing, or eliminating conflicts of interest
- **Equity Interest:** Includes stock, stock options, warrants, partnership, or other ownership interests. Equity assets or income from investment vehicles such as mutual funds and retirement accounts do not require disclosure if the investigator does not control the investment decisions made in these vehicles.
- **Immediate Family:** An individual's spouse and dependent children
- **Institutional Responsibilities:** An individual's responsibilities on behalf of the University, including, but not limited to, teaching, service or consulting for external entities, administration, professional practice, and membership on University committees.
- **Institutional Official:** The Associate Provost for Research and Economic Development is designated as the Institutional Official for externally-sponsored projects and is responsible for ensuring the submission and review of disclosures

and actions taken in response to potential conflicts of interest in accordance with this Policy.

- **Investigator:** Any person responsible for the design, conduct, or reporting of research or educational activities funded by an external sponsor. The application of this definition requires consideration for the individual's role in a sponsored project, not title.
- **Management Plan:** A document developed and agreed to by an investigator and the CIRC, which constitutes a plan for the resolution of an identified conflict of interest
- **Office of Record:** The University office designated to maintain files, actions, and records pertaining to conflict of interest disclosures, reviews, determinations, management plans, and reporting. The Division of Sponsored Programs will be the University Office of Record.
- **Potential Conflict of Interest:** Results from a disclosure which, after review by the Director of Sponsored Programs and Institutional Official, indicates there is either enough evidence, or enough doubt, to require further review by a University Conflict of Interest Review Committee (CIRC)
- **Public Health Service (PHS):** Agencies that are operating units of the U.S. Department of Health and Human Services, including Agency for Healthcare Research and Quality (AHRQ), Agency for Toxic Substances and Disease Registry (ATSDR), Centers for Disease Control and Prevention (CDC), Food and Drug Administration (FDA), Health Resources and Services Administration (HRSA), Indian Health Service (IHS), National Institutes of Health (NIH), Substance Abuse and Mental Health Services Administration (SAMHSA)
- **Significant Financial Interest:** Anything of monetary value, including, but not limited to: (1) Salary or other payments for services (e.g., consulting fees/honoraria); (2) Equity interests (e.g., stocks, stock options or other ownership interests); and (3) Intellectual property rights (e.g., patents, copyrights, and royalties from such rights)

## Violations of the Policy

Violations of this Policy will result in sanctions being imposed upon the violating individuals. Examples of violations may include, but are not limited to, an investigator's negligence in completing required disclosures and/or training, willful concealment of financial interests, negligence in reporting new financial interests, or failure to comply with the requirements of a conflict of interest management plan.

Upon discovery of non-compliance, the University shall begin a retrospective review that shall be completed within 120 days of the discovery. The Chair of the CIRC shall be responsible for organizing the CIRC for the purpose of reviewing the violation. The CIRC shall make written recommendations to the Institutional Official, who will confer with the Executive Vice President for Academic Affairs/Provost prior to the imposition of sanctions. The ultimate decision regarding sanctions to be imposed will be that of the Executive Vice President for Academic Affairs/Provost and will be based on the requirements of University and sponsoring agency policies. The decision by the

Executive Vice President for Academic Affairs/Provost may be appealed to the President.

If an investigator's non-compliance has directly biased the design, conduct, or reporting of an externally-funded research or educational activity, the University shall promptly notify the sponsoring agency of the conflict, non-compliance, and corrective action. This notification process shall be the responsibility of the Chair of the CIRC. In cases involving PHS-funded clinical trials for which an investigator is found to have a financial conflict of interest, the investigator shall be required to disclose the conflict in all publications or public presentations of the results. For any previously published results, the investigator shall be required to request an addendum from the publisher.

## Resources

- [National Science Foundation: Conflict of Interest Policy](#)
- [Public Health Services: Promoting Objectivity in Research Policy](#)
- [University Financial Conflict of Interest Reporting and Training](#)

## Regulation Adoption Review and Approval

### Regulation Revised

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November 2001

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Unknown

**ACTION**

Revision

### Regulation Issued

**DATE**

October 28, 1995

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Board of Regents

President Funderburk

Faculty Senate

**ACTION**

Adopted

Approved

Approved