

EASTERN MICHIGAN UNIVERSITY
CONFLICT OF INTEREST DISCLOSURE FORM
FOR FEDERALLY SPONSORED PROJECTS

Name _____ Title and/ or Rank _____

College _____ Department/ Unit _____

e-mail address _____

1. Do you have a consulting or other financial relationship with a sponsor of your research?

_____ yes (*If so, please list and explain in an attached statement.*)

_____ no

2. Do you have a managerial role or a significant financial relationship with a company in a field of your research or a company that does business with the University?

_____ yes (*If so, please list and explain in an attached statement.*)

_____ no

3. Are you engaged in non-University professional or income-producing activities involving either Eastern Michigan University students or other staff?

_____ yes (*If so, please list and explain in an attached statement.*)

_____ no

4. Do you or any members of your immediate family have any other relationships, commitments, or activities that might present or appear to present a conflict of interest or commitment related to this grant or grant proposal?

_____ yes (*If so, please list and explain in an attached statement.*)

_____ no

5. I have read and understand Eastern Michigan University's Investigator Significant Financial Disclosure Policy for Federally Funded Projects and have made all financial disclosures required by that policy, if any, in an attached statement. I will comply with any conditions or restrictions imposed by the University to manage, reduce or eliminate actual or potential conflicts of interest.

Signature

Date

EMU
INVESTIGATOR FINANCIAL DISCLOSURE POLICY
FOR FEDERALLY FUNDED PROJECTS

These guidelines set forth Eastern Michigan University's general policy and procedures regarding significant financial conflicts of interest in relation to federally sponsored projects.

Their purpose is to protect the credibility and integrity of the University's researchers and staff members and of the University itself so that public trust and confidence in the University's sponsored research activities is ensured.

In accordance with federal regulations, Eastern Michigan University has a responsibility to manage, reduce, or eliminate any conflicts of interest that may be presented by a financial interest of an investigator.

Thus, the University requires that investigators disclose any significant financial interest that may present a conflict of interest in connection with a federally sponsored project.

Background

On July 11, 1995, the National Science Foundation (NSF), the National Institutes of Health (NIH), the Public Health Service (PHS), and the Department of Health and Human Services (HHS) issued notice of their revised policies on financial disclosure by scientific investigators in sponsored research, which are designed to protect the integrity of funded research and, at the same time, to promote sharing and publication of research results. The notice, entitled Investigator Financial Disclosure Policy, is effective October 1, 1995.

Placing primary responsibility on each institution to develop data-gathering, reporting, and enforcement procedures, the agencies listed above require that grantee institutions employing more than fifty persons maintain "an appropriate written and enforced policy on conflict of interest." They also require assurance by applicant institutions that there is no reasonable expectation that the design, conduct, and reporting of research to be funded will be biased by any significant financial interest of the investigator responsible for the design, conduct, and reporting of the research. Researchers and institutional representatives must comply with the institutional requirements.

Requirements

Federal regulations require institutions to have policies and procedures in place that ensure that investigators disclose any significant financial interest that may present a conflict of interest in relationship to federally sponsored projects. Such disclosures must be made prior to the submission of a proposal for funding; and institutions must certify compliance on each proposal, as well as develop specific mechanisms by which conflicts of interest will be satisfactorily managed, reduced, or eliminated, prior to the University's expenditure of any funds under an award. The institution must also maintain appropriate records. If a new or reportable conflict of interest arises at any time during

the period after submission of the proposal through the period of the award, the filing of a disclosure is also required.

Definitions

The term investigator refers to the principal investigator/project director, co-principal investigator(s), and 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 an external sponsor. In this context, the term investigator includes the investigator's spouse and dependent children.

A conflict of interest may take many forms, but arises when a principal investigator is or may be in a position to influence University business, research, or other decisions in ways that could lead to any form of personal gain for the principal investigator (including his/her spouse and/or dependent children) or give improper advantage to others to the University's detriment.

A potential conflict of interest occurs when there is a divergence between an individual's private interests and his or her other professional obligations to the institution such that an independent observer might reasonably question whether the individual's professional actions or decisions are determined by considerations of personal gain, financial or otherwise. An actual conflict of interest depends on the situation, and not on the character or actions of the individual.

An actual or potential conflict of interest exists when the reviewers of disclosures determine that a significant financial interest could reasonably appear to affect the design, conduct, or reporting of the research or educational activities funded or proposed for funding by an external sponsor.

Significant financial interest means anything of monetary value, including, but not limited to, salary or other payment for services (e.g., consulting fees or honoraria); equity interests (e.g., stocks, stock options, or other ownership interests); and intellectual property rights (e.g., patents, copyrights, and royalties from such rights).

The term significant financial interest does not include:

- salary, royalties, or other remuneration from Eastern Michigan University
- 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; or
- financial interests in business enterprises or entities if the value of such interests does not exceed \$10,000 (or \$10,000 per annum if such interests represent salary, fees, or other continuing payments) or represent more than 5% ownership interest for any one enterprise or entity when aggregated for the investigator and the investigator's spouse and dependent children.

Example: An investigator who owns an equity interest which is worth \$20,000 (with reference to public prices or other reasonable measures of fair market value), but which represents only one

percent ownership in the entity, would nevertheless be required to disclose that interest if it would reasonably appear to be affected by the research or educational activities funded or proposed for funding" (NSF Grant Policy Manual 510).

Significant financial interests that must be disclosed are: (a) any financial interests of the investigator (including the investigator's spouse and dependent children) that would reasonably appear to be directly and significantly affected by the research or educational activities funded or proposed for funding by the external sponsor; or (b) entities whose financial interests would reasonably appear to be directly and significantly affected by the sponsored activities. Research funded under the Small Business Innovation Research Program or Small Business Technology Transfer Program is excluded from this disclosure.

Policy

Effective October 1, 1995, Eastern Michigan University requires each investigator submitting a proposal for funding by a federal agency to submit all required financial disclosures at the time of proposal submission and to update this information annually, or as new reportable interests are obtained, during the life of the award.

Disclosure of financial interests shall be made to the Director of the Office of Research Development (or official designee) by means of a packet of information consisting of the Conflict of Interest Disclosure Form for Federally Sponsored Projects, all required supporting documentation (in a sealed envelope marked confidential), the proposal, and the proposal transmittal form.

In accordance with federal regulations, a complete disclosure must be made by the investigator(s) prior to the submission of the proposal. At the time a proposal is submitted to a federal funding agency, the Director of the Office of Research Development shall certify that the University has implemented a written and enforced conflict of interest policy that is consistent with current federal guidelines.

The procedure to review disclosures, assess their potential for conflicts of interest, and develop strategies to manage, reduce, or eliminate such conflicts shall be incorporated with the standard internal University review process and integrated into the normal submission process.

A Conflict of Interest Review Committee shall be charged with the responsibility for review of financial disclosure to determine whether an actual or potential conflict of interest exists; to determine what conditions or restrictions, if any, should be imposed by the institution to manage, reduce, or eliminate such conflicts of interest; and, as necessary, to recommend sanctions.

In the event that a conflict of interest cannot be resolved to the satisfaction of the committee, the administrative officer of the committee shall direct the Director of the Office of Research Development to inform the funding agency of the unresolved issues prior to the University's expenditure of any funds under the award.

The Office of Research Development shall be responsible for appropriate follow-up reporting and records-management procedures. Records of investigator financial disclosures and actions taken to manage actual or potential conflicts of interest shall be retained for at least three years beyond the termination or completion of the grant to which they relate, or until the resolution of any government action involving those records, whichever is longer. All records shall be maintained in a manner to protect confidentiality.

Guidelines

1. Each investigator is required to disclose the following financial interests:

- Any significant interest of the investigator that would reasonably appear to be affected by research or educational activities funded, or proposed for funding, by an external sponsor; or
- Any significant financial interest of the investigator in an entity whose financial interest would reasonably appear to be affected by the research or educational activities funded, or proposed for funding, by the external sponsor.

2. Regardless of the above minimum requirement, a faculty or staff member, in his or her own best interest, may choose to disclose any other financial or related interest that could present a conflict of interest. Disclosure is a key factor in protecting one's reputation and career from potentially embarrassing or harmful allegations of misconduct.

Each investigator shall complete a Significant Financial Interests Disclosure Form and attach all required supporting documentation. The completed disclosure form must be submitted with the proposal and proposal approval form to the Office of Research Development using normal University procedures.

Supporting documentation that identifies the business enterprise or entity involved and the nature and amount of the interest shall be submitted in a sealed envelope marked confidential and accompany the disclosure form, the proposal, and the proposal transmittal form.

3. As required by federal regulation, all significant financial interests must be disclosed prior to the time a proposal is submitted. All financial disclosures must be updated by investigators during the period of the award, either on an annual basis or as changes are made to previously reported significant financial interests. If a new reportable significant financial interest arises at any time after the submission of the proposal through the entire period of any resulting award, the filing of a disclosure form is also required.

4. At the time a proposal is submitted to a federal agency, the Director of the Office of Research Development shall certify that the University has implemented a written and enforced conflict of interest policy that is consistent with current federal guidelines (including the provisions of the National Science Foundation's Grant Policy Manual 510); that to the best of his/her knowledge, all financial disclosures required by the University's Conflict of Interest Policy have been made; and

that all identified conflicts of interest have been satisfactorily managed, reduced, or eliminated prior to the University's expenditure of any funds under the award.

5. Once a project has been funded, the Director of the Office of Research Development or his/her official designee shall conduct an initial review of all financial disclosures to determine if any disclosed significant financial interest could affect the design, conduct, or reporting of the proposed sponsored project. If the initial determination is made that there may be a potential conflict of interest as defined in this policy, then the Director of the Office of Research Development shall notify the investigator and the investigator's department head or dean (see section 6 below). The Director of the Office of Research Development shall also refer the disclosure packet to the Conflict of Interest Review Committee.

Faculty members of the Conflict of Interest Review Committee are recommended by Faculty Council and appointed by the Provost. The committee shall include EMU faculty researchers representing a cross section of disciplines and EMU administrators including, but not limited to, a research administrator. The committee shall determine what conditions or restrictions, if any, should be imposed by the institution to manage, reduce, or eliminate any conflict of interest arising from the disclosed significant financial interests.

If the investigator believes the determined course of action is inappropriate, the investigator may appeal by requesting that the decision be reconsidered by the committee. In the event that an actual or potential conflict of interest cannot be resolved to the satisfaction of the committee, the administrative officer of the committee shall direct the Director of the Office of Research Development to inform the funding agency of the unresolved issues.

6. Prior to consideration by the Conflict of Interest Review Committee, the investigator, in cooperation with the investigator's department or college, shall develop and present to the committee a resolution plan that details proposed steps that will be taken to manage, reduce, or eliminate any actual or potential conflict of interest presented by a significant financial interest.

At a minimum, the resolution plan shall address such issues as public disclosure of significant financial interests, review of research protocol by independent reviewers, and monitoring of research by independent reviewers.

Where the committee deems appropriate, the committee shall review the resolution plan and approve it, or add conditions or restrictions, of which the following are possibilities: (a) modification of the research plan; (b) disqualification from participation in all or a portion of the research funded; (c) divestiture of significant financial interests; or (d) severance of relationships that create conflicts of interest.

7. The University expects investigators to comply fully and promptly with all the requirements of this policy. Breaches of this policy include, but are not limited to, failure to file, intentionally filing an incomplete, erroneous, or misleading disclosure form, or failing to provide additional information as required by the approving authority. Violating this policy may result in discipline for the investigator. If sanctions are necessary, they will be imposed in accordance with the provisions of

Article XVI of the collective bargaining agreement between Eastern Michigan University and the Eastern Michigan University Chapter of the American Association of University Professors. The potential sanctions include, but are not limited to, the following: letter of admonition; letter to funding agency; ineligibility of the investigator for grant applications; ineligibility for institutional approval; suspension. If a conflict of interest cannot be resolved to the satisfaction of the University, the funding agency shall be appropriately informed.

8. The Office of Research Development shall be responsible for appropriate follow-up reporting and records-management procedures. Records of investigator financial disclosures and actions taken to manage conflicts of interest shall be retained until three years after the termination or completion of the award to which they relate, or the resolution of any government action involving those records. All records shall be maintained in a manner to protect confidentiality.

Conflict of Interest Disclosure Procedure

Prior to the submission of a proposal for federal funding, a disclosure form and supporting documents are submitted to the Office of Research Development (ORD).

The ORD Director (or designee) conducts the initial review. If the initial review indicates a potential for conflict of interest, then the ORD Director notifies the applicant and the applicant's dean or department head. The ORD Director forwards the applicant's confidential packet to the Conflict of Interest Review Committee.

Prior to consideration by the Conflict of Interest Review Committee, the investigator, in cooperation with the investigator's department or college, develops and presents to the Review Committee a resolution plan that details proposed steps that will be taken to manage, reduce, or eliminate any actual or potential conflict of interest presented by a significant financial interest. At a minimum, the resolution plan shall address such issues as public disclosure of significant financial interests, review of research protocol by independent reviewers, and monitoring of research by independent reviewers.

(Further information can be found in "Eastern Michigan University Policy Manual.")