+2707623471

T_700 P 002/016 E_66

James L. Booth, Provo

September 28, 1995

MSU CONFLICT OF INTEREST POLICY

Introduction

Murray State University encourages interaction with both the public and private sectors as an important component of all education activities, public-service activities, and research activities. Accordingly, the university is committed to conducting its sponsored projects within the highest standards of integrity. This includes identifying potential 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 Form (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 sponsored 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, it desires 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 are defined as follows:

- A <u>University</u> Murray State 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. <u>Associated Entity</u> Any trest, organization, or enterprise (other than the university) over which the investigator, or any member of the immediate family, exercises a controlling interest.
- 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 toyalties 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 nopprofit 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.
- Investigator Principal investigator/project director, co-principal investigator, co-E. project director, or any other person, including subgrantees or subcontractors, responsible for the design, conduct, or reporting of research or educational activities funded by an external sponsor.
- Immediate Family Principal investigator's/project director's spouse or domestic 下. partner, co-principal investigator's/co-project director's spouse or domestic partner, and/or dependent children.
- Negative Disclosure Refers to Financial Disclosure Form (Attachment B) which, G. after review, indicates no conflict of interest on the part of the investigator.
- Positive Disclosure Refers to Financial Disclosure Form (Attachment B) which, H. 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 pentaining 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 office of the Provost will be the university Office of Record.
- J. Conflict-of-Interest Review Committee (CIRC) The Conflict-of-Interest Review

 Committee (CIRC) will be appointed by the Provost. The Chair of the Conflict-ofInterest Review Committee shall be the Director of Sponsored Programs. The

 General 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 lew, 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 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 <u>may</u> 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.
- 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 Murray State 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 MSU's Proposal Routing/Approval Form in order to initiate the review process. During the proposal routing process, the Financial Disclosure Form will be reviewed by the immediate supervisor (e.g., Chair, Director), the next-level supervisor (e.g., Dean), 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.

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 (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 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 the purpose 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. Α.
- Consider the nature, and extent, of the financial interest in the relationship between B. the investigator and the external sponsor
- Disapprove the Financial Disclosure Form as revealing an unresolvable conflict of Ç. 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.

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 Provost. The Provost 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 Provost 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 Provost, who will confer with the President prior to the imposition of any sanctions. The ultimate decision regarding sanctions to be imposed will be that of the President and will be in keeping with the <u>Murray State University Faculty Handbook</u>. The decision by the President may be appealed through the appropriate university channels.

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 being 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 <u>unable</u> to satisfactorily manage, reduce, or eliminate a conflict-of-interest situation.

Attachment A

FINANCIAL DISCLOSURE SUMMARY INFORMATION

(Applicable to all Sponsored Project Proposals)

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 filling of an updated. Financial Disclosure Form is also required. In cases of multi-year funding, a review of an investigator's simulation must take place annually.

Who is covered?

"Investigator" means the principal investigator/project director, co-principal investigator/coproject 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:

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 Honoria); 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 does not include:

- salary, royalties, or other remuneration from the institution;
- income from seminars, lectures, or teaching engagements sponsored by public or nonprofit cuticies;
- (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 12month 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 MSU's Proposal Routing/ 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.