

UAR NUMBER: 119.01

TITLE: Conflicts of Interest/Financial Disclosures in Projects with External Funding

ORIGINATOR: Executive Vice President for Academic Affairs

INITIAL ADOPTION: 09/27/1995

REVISION DATES:

PURPOSE: To establish standards and procedures in compliance with applicable Federal regulations regarding the management of conflicts of interest and/or conflicts of financial interest in projects with external funding.

PROCEDURAL REFERENCES FOR:

BOR, Pg-12 (Conflict of Interest)

Other, Federal Regulations: Public Health Services, Department of Health and Human Services and the National Science Foundation (42 CFR Part 94)

SCOPE (Who is covered by this UAR?) Morehead State University faculty and staff involved in externally funded projects.

Background: Effective October 1, 1995, Federal regulations require Morehead State University to identify, manage, reduce, or eliminate any conflicts of interest that may be presented by a financial interest of an investigator of an externally funded project. Accordingly, Federal agencies require that grant applicants adopt and enforce standards and procedures regarding conflicts of interests and/or conflicting financial interests. This includes the identification of conflicts of interest, and further, ensuring that the conflicts of interests of an investigator do not reasonably appear to affect the objectivity of the funded research or educational activities. Morehead State University is committed to conducting its externally funded projects, public and private, in compliance with these Federal regulations.

Federal Regulations: The following Federal regulations provide the basis for the establishment of the standards and procedures regarding the management of Conflicts of Interest/Financial Disclosure in projects with external funding.

Objectivity in Research; Final Rule, Department of Health and Human Services, Public Health Service, Federal Register, July 11, 1995, 60 (132) 35810-35819.

Investigator Financial Disclosure Policy; Notice of Technical Changes, National Science Foundation, Federal Register, July 11, 1995, 60 (132) 35820-35823

Purpose: Morehead State University has no interest in setting forth detailed rules and procedures that may interfere with faculty and staff members' legitimate outside interests; rather, its desire is to protect the credibility of the University and its investigator(s) while complying with mandated regulations governing externally funded projects. The University has a clear responsibility to identify, manage, reduce, and/or eliminate conflicts of interest and/or conflicting interest. It is the purpose of these administrative regulations 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 interests. These regulations apply to all research and educational activity

projects funded through external grants and contracts.

Definitions: The terms used in these administrative regulations are defined as follows:

1. Conflict of Interest - A conflict of interest exists if the reviewer(s) of disclosures determines 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.
2. 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.
3. Significant Financial Interest - Anything of monetary value, including, but not limited to:
 - A. Salary or other payments for services (e.g., consulting fees or honoraria);
 - B. Equity interests (e.g., stocks, stock options or other ownership interests);
 - C. Intellectual property rights (e.g., patents, copyrights, and royalties from such rights).

This term does **not** include:

- A. Salary, royalties or other remuneration from the institution;
 - B. Any ownership interest in a business enterprise which is an applicant under the Small Business Innovation Research Program or the Small Business Technology Transfer Program;
 - C. Income from seminars, lectures, or teaching engagements sponsored by public or nonprofit entities;
 - D. Income from service on advisory committees or review panels for public or nonprofit entities;
 - E. 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
 - F. 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.
4. Investigator - 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 of research or educational activities funded by any external agency.
 5. Immediate Family - Principal investigator's/project director's spouse, co-principal investigator's/co-project director's spouse and/or dependent children.
 6. Negative Disclosure - Refers to Financial Disclosure Form (available in the Office of Research, Grants and Contracts) that, after review, indicates no conflict of interest on the part of the investigator.
 7. Positive Disclosure - Refers to Financial Disclosure Form (available in the Office

of Research, Grants and Contracts) that, after review, indicates there is either enough evidence, or enough doubt, to require further review by a University Conflict of Interest Review Committee.

8. Conflict of Interest Review Committee - In accordance with the University committee structure, the Conflict of Interest Review Committee is an advisory committee recommendatory to the Executive Vice President for Academic Affairs and Dean of Faculty.

The committee will review all positive conflict of interest disclosures for the purpose of managing, reducing, or eliminating potential conflicts of interest. Voting membership of the committee shall consist of one faculty member from each college, a professional librarian, and one staff member from the Division of Academic Affairs, appointed annually by the President, and the Director of Research, Grants and Contracts. The Chair of the Conflict of Interest Review Committee shall be the Director of Research, Grants and Contracts. University Council will be available to advise the committee on a need basis. A majority of the committee will constitute a quorum and the chair will vote only in the case of a tie.

9. Office of Record - The University office designated to maintain files, actions, and records pertaining to the Investigator Financial Disclosure Form completed by an investigator. Records, including the Investigator 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 Research, Grants and Contracts will be the Office of Record.
10. Confidentiality of Records - To the extent permitted by law, the Office of Record will maintain the confidentiality of all records of financial interests.
11. Conflict of Interest Plan - A plan developed by the Conflict of Interest Review Committee, in cooperation with the investigator, for resolution of an identified conflict of interest.
12. Designated Institutional Official - An official designated by the University to solicit and review financial disclosures from each investigator to identify conflicting interests and take such actions necessary to insure that such conflicting interests will be managed, reduced, or eliminated. The Director of Research, Grants and Contracts will be the designated institutional official.

Disclosure and Review: In those instances where the University is engaged in, or intends to engage in an externally funded project or has subcontracted or intends to subcontract with an external agency, a conflict of interest may occur if the investigator's affiliation with the external agency specifically meets any of the following criteria:

1. The investigator is an officer, director, partner, trustee, employee, advisory board member, or agent of the external agency funding a project in which the investigator is participating in any capacity.
2. 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.

3. The investigator derives income or other payments that, when aggregated for the next 12 months, is expected to be more than \$10,000.
4. The investigator's immediate family meets any of the criteria outlined in 1-3 above.

It is the responsibility of those investigators of Morehead State University, either full- or part-time faculty or staff, who will be participating in an externally funded project covered by these administrative regulations, to initiate the disclosure process through the Office of Research, Grants and Contracts via an Investigator Financial Disclosure Form at the time of proposal submission indicating whether or not they have external affiliations which could constitute a conflict of interest as addressed in the above criteria.

The disclosure procedures include the following steps:

1. The investigator completes and routes the Investigator Financial Disclosure Form as part of the University's normal internal proposal review and routing process, which occurs approximately two weeks prior to proposal submission.
2. The Investigator Financial Disclosure Form will provide evidence to support a Negative Disclosure (reveals no financial conflict) or a Positive Disclosure (requires additional review by the Conflict of Interest Review Committee).
3. Negative Disclosures will be filed in the Office of Record (Office of Research, Grants and Contracts).
4. Positive Disclosures will be reviewed by the Conflict of Interest Review Committee convened by the chair. The committee will be guided by the following practices and apply them as necessary:
 - A. Assure adherence to all relevant governmental and University policies and regulations.
 - B. Consider the nature, and extent, of the financial interest in the relationship between the investigator and the external agency.
 - C. Obtain additional information from the investigator as may be necessary in resolving conflicts.

Upon completion of its review, the Conflict of Interest Review Committee will recommend one of the actions to the Executive Vice President for Academic Affairs:

- A. Approval of the investigator Financial Disclosure Form.
- B. Approval of the Investigator Financial Disclosure Form subject to modifications which might be imposed to manage, reduce, or eliminate conflicts of interest.
- C. Disapproval of the Investigator Financial Disclosure Form as revealing an unresolvable conflict of interest.

When any of the above-mentioned options are exercised, the Executive Vice President for Academic Affairs will advise the investigator and the funding agency.

If an investigator's financial situation changes in terms of new reportable Significant Financial Interests, after the submission of an Investigator Financial Disclosure Form, it is the responsibility of that investigator to update his/her situation by immediately submitting a new Investigator Financial Disclosure Form to the Director of Research,

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

Appeals Process: Investigators dissatisfied with the recommendation of the Conflict of Interest Review Committee may appeal in writing to the Executive Vice President for Academic Affairs. The Executive Vice President will confer with the investigator and the Conflict of Interest Review Committee to the extent necessary to render a decision in compliance with the Federal regulations governing conflicts of interest. The decision of the Executive Vice President will be final.

Violations of Regulations: Any violations of these administrative regulations, such as willful concealment of financial interest by an investigator, may result in sanctions being imposed upon the investigator. The Conflict of Interest Review Committee will review any alleged violations brought to its attention. The Committee will recommend sanctions to the Executive Vice President for Academic Affairs. The final decision regarding sanctions to be imposed will be made by the Executive Vice President for Academic Affairs and will be in keeping with the Morehead State University policies.

In the failure of an investigator to comply with the conflict of interest regulations 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 funding agency of the corrective action taken. This notification process will be the responsibility of the Executive Vice President for Academic Affairs.

Funding Agency Requirements: Some funding agencies, particularly governmental agencies, may have requirements that differ from these administrative regulations with regard to the timing and/or frequency of disclosures and other provisions. When differences occur, the funding agency's requirements shall prevail.

Prior to the University's expenditure of any funds under an award, grant or contract, the Executive Vice President for Academic Affairs will report to the relevant funding agency the existence of a conflicting interest (but not the nature of the interest or other details) found by the University and assure that the interest has been managed, reduced, or eliminated; and, for any interest that the University identifies as conflicting subsequent to the University's initial report under the award, the report will be made and the conflicting interest managed, reduced, or eliminated, at least on an interim basis, within sixty days of that identification.

Records: In accordance with Federal regulations, Morehead State University will maintain records of all financial disclosures and of all actions taken to resolve conflicts for at least three years from the date of submission of the final expenditure report or the resolutions of any civil, government, or University action involving those records. The Office of Research, Grants and Contracts will be the Office of Record.

