

SYSTEM REGULATION

15.01.03 Conflict of Interest In the Design, Conduct and Reporting of Sponsored Research and Educational Activities

July 31, 1996

Supplements System Policy 15.01

1. PURPOSE AND BACKGROUND

- 1.1 The System recognizes its responsibilities as a public organization to encourage interaction between its employees and the public and private sectors as an important component of its research, instructional and service activities. The System encourages the recruitment, retention and recognition of individuals with creative abilities who can contribute to technology transfer and interactions with the business community and public entities consistent with their primary commitment to the System. The System and its employees are also committed to conducting themselves and their activities in a manner consistent with the highest standards of integrity and ethics.
- 1.2 These guidelines define the general regulations and procedures regarding conflicts of interest in relation to sponsored research. Their purpose is to protect the credibility and integrity of System researchers and staff, as well as component universities and agencies themselves, so that public trust and confidence in their sponsored research activities are maintained. System components have a responsibility to manage, reduce or eliminate any actual or potential conflicts of interest that may arise due to a financial or other personal interest of an investigator. Therefore, the System requires that investigators disclose any significant financial interest that might create a real or potential conflict of interest in relation to a sponsored project.
- 1.3 These guidelines apply specifically to research conducted under contracts and grants from the National Science Foundation (NSF) and the Public Health Service (PHS); however CEOs may, at their option, extend the application of these guidelines to all sponsored research.
- 1.4 In addition to issues addressed in these regulations, there may be ethical considerations that are distinct and separate from conflict of interest questions.

2. DEFINITIONS

- 2.1 A potential *conflict of interest* occurs when an individual's private interests compete with his/her professional obligations to the System to a degree 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. This regulation is to address such conflicts when a significant financial interest reasonably appears to affect or bias the design, conduct or reporting of research or educational activities funded or proposed for funding to sponsoring agencies.

2.2 *Investigator* means the principal investigator/project director, co-principal investigator, and any other person affiliated with the System who has authority and responsibility for the design, conduct or reporting of research or educational activities funded or proposed for funding to sponsoring agencies. In this context, "Investigator" also includes the investigator's spouse and dependent children.

2.3 *Significant Financial Interest*

2.3.1 Significant Financial Interest means anything of monetary value, including but not limited to, salary or other payments for services (e.g., consulting fees or honoraria from profit-making enterprises); equity interests (e.g., stocks, stock options or other ownership interests); and intellectual property rights (e.g., patents, copyrights and royalties from such rights). These regulations adhere to the definitions put forth in the guidelines of the National Science Foundation and the Department of Health and Human Services, which say that the possibility of a potential conflict of interest exists when financial interests in business enterprises or entities meet the following conditions:

- (1) An equity interest that when aggregated for the Investigator and the Investigator's spouse and dependent children, 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 five percent ownership interest in any single entity; or
- (2) Salary, royalties or other payments that when aggregated for the Investigator and the Investigator's spouse and dependent children over the next twelve months, are expected to exceed \$10,000.

2.3.2 The term *does not* include:

- (1) Salary, royalties or other remuneration from the System;
- (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.

2.3.3 Examples of Conflict of Interest, include, but are not limited to, the following:

Example 1. Situations where a substantial body of research that could and ordinarily would be conducted by the investigator within a System component is diverted elsewhere.

Example 2. Situations where the investigator occupies a position in an enterprise doing business in the area of the investigator's University.

- Example 3. Relationships that might enable investigators to influence a System component's interactions with outside organizations in ways that may lead to personal gain, to the taking of improper advantage by anyone, or the improper diversion of a System component's assets from the primary missions of a System component, including the time and talents of faculty and staff.
- Example 4. Situations in which an investigator, while serving as a consultant to an external organization, has access to a colleague's unpublished, privileged information, such as proposals or papers that have potential value, and the investigator seeks to provide that information to the external organization.
- Example 5. Situations where an investigator directs students into a research area or other activity from which the investigator intends to realize personal financial gain. A conflict may arise if students are directed to areas of lesser scientific or scholarly merit to enhance the potential for monetary gain or if the financial potential exists only for the investigator.
- Example 6. Disclosure or use for personal profit of unpublished information coming from System research or other confidential System sources, or assisting outside organizations by giving them access to such information except as may be authorized by official System policies.
- Example 7. Consultation that imposes obligations that conflict with the System Policy on patents (System Policy 17.02) or with a System component's obligations to research sponsors.
- Example 8. Situations in which an investigator can require others to purchase a product in which the investigator has a proprietary interest and from which the investigator will receive income.

3. GUIDELINES

Each component university and agency of the System that performs research or educational activities funded by grants and contracts shall establish rules and procedures for the disclosure by researchers of financial interests that might reasonably appear to be directly and significantly affected by the research or educational activities funded under the grant or contract. Such rules and procedures shall address the following issues related to the disclosure and review of such interests.

3.1 Disclosure of Financial Interests

The possibility of a potential conflict of interest should be noted and disclosed by the investigator at the earliest possible stage, and no later than at the time of proposal submission. If a potential conflict of interest does exist with a proposed or funded project, each investigator is required to disclose the following information about any entity which would reasonably appear to have a financial interest that would be directly and significantly affected by the research or educational activities being funded:

- (1) the names of affected corporations, both for-profit and not-for-profit, for which the person serves as a member of the governing board in the capacity of a director, advisory director, trustee, or otherwise;
- (2) the names of affected corporations for which the person serves as an officer;
- (3) the name of affected partnerships, limited partnerships, proprietorships, or other business associations of which the person is a partner, general or limited partner, joint venturer, or owner;
- (4) the amount of any compensation received for services related to (1), (2), and (3) above, including any benefits, direct or indirect (reported by range of amounts) and benefits received for intellectual property rights (e.g., patents, copyrights, and royalties from such rights);
- (5) affected business entities in which the person holds a controlling interest or is the principal shareholder;
- (6) whether the person is employed by any affected business entities described in (1) through (5) above that have any relationship to the System or any of its components, and a brief description of such relationship.

3.1.1 The information should be provided for investigators, their spouses, and their dependent children.

3.1.2 Questions regarding specific potential conflict of interest situations may be clarified by consulting with an individual or office designated by the CEO. The System Office of General Counsel may be consulted when needed.

3.1.3 Each investigator shall complete separate Significant Financial Interests Disclosure Forms for himself/herself, his/her spouse and his/her dependent children, attaching all required supporting documentation.

- 3.1.4 All pertinent Significant Financial Interests must be disclosed at the time each proposal with potential conflict of interest is submitted for internal routing. Annual updates must be filed by all investigators by August 31 of each year, by filing a supplemental disclosure form through the Department Head and College Dean to the Director of Sponsored Projects.
- 3.1.5 Subawardees, contractors, or collaborators included in proposals submitted by the component shall certify that their organization has a Conflict of Interest Policy in compliance with the Federal regulations prior to the submission of the proposal.

3.2 Review of Disclosure

- 3.2.1 The CEO shall designate an officer who 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 for conflict of interest covered by this Regulation, the investigator will be notified and the Disclosure packet will be referred to the component Conflict of Interest Review Committee (CIRC).
- 3.2.2 Conflict of Interest Review Committee members and chair are appointed by the CEO or designee. The CIRC shall be composed of researchers representing a cross section of disciplines and a research administrator.
- 3.2.3 The CIRC shall determine what conditions or restrictions, if any, should be imposed by the institution to manage actual or potential conflicts of interest arising from disclosed Significant Financial Interests.
- 3.2.4 Prior to consideration by the CIRC, the Investigator, in cooperation with the Investigator's supervisor, shall develop and present to the CIRC a Resolution Plan detailing the proposed steps that will be taken to manage, reduce or eliminate any actual or potential conflict of interest presented by the Significant Financial Interest. The Resolution Plan shall include as appropriate:
 - (1) public disclosure of Significant Financial Interests;
 - (2) review of research protocol by independent reviewers;
 - (3) monitoring of research by independent reviewers;
 - (4) modifying the research plan;
 - (5) disqualification from participating in all or a portion of the research funded;
 - (6) divestiture of significant financial interests; and

(7) severance of relationships that create actual or potential conflicts of interest.

3.2.5 The CIRC shall review the Resolution Plan and approve it, or where appropriate, add or delete conditions or restrictions.

3.2.6 If the CIRC determines that imposing the above-referenced conditions or restrictions would be inequitable, or 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, the CIRC may recommend that the research go forward without imposing such conditions or restrictions but managed with appropriate monitoring of the research to ensure that the financial interest does not bias the project. In cases where the Investigator feels that the CIRC decision was unfair, the case may be appealed to the CEO who shall make the final decision regarding resolution. All non-resolved conflicts will be immediately reported to the funding agency or agencies.

3.2.7 The approved Resolution Plan shall be incorporated into a Memorandum of Understanding (MOU) that details the conditions or restrictions imposed upon the Investigator in the conduct of the project or in the relationship with the Business Enterprise or Entity. The Memorandum of Understanding shall be signed by the Investigator, the Investigator's supervisor and the Chairperson of the CIRC. Actual or potential conflicts of interests will be satisfactorily managed, reduced or eliminated in accordance with these Guidelines prior to the expenditure of any funds under the award, or these actual or potential conflicts of interest will be disclosed to the sponsoring agency for action.

3.2.8 A CEO may establish a plan for review that does not involve a standing CIRC, provided all elements of disclosure and review are observed and that an ad hoc committee is named to handle unresolved questions of financial conflict.

3.3 Record Keeping

Records of Investigator financial disclosures and of actions taken to manage actual or potential conflicts of interest shall be retained by the System component until 3 years after the termination or completion of the award to which they are related, or the resolution of any government action involving those records.

3.4 Enforcement

3.4.1 Apparent oversights or violations of this regulation and applicable university or agency rules shall be brought to the attention of the Investigator, who will be afforded an opportunity to comply. The Investigator shall present the proposed correction to the CIRC for review and action within 30 calendar days of the notification. Failure to comply will constitute an intentional violation, as discussed in the following paragraph.

- 3.4.2 Repeated or intentional violations of this regulation may be reported to the funding agency and the CEO by the CIRC if not corrected. Sanctions may be imposed by the CEO and may range from a letter of reprimand to the removal of an Investigator from an ongoing project.
- 3.4.3 Cases that involve investigators affiliated with a System component and which include the possibility of scientific or academic misconduct shall be processed in a manner consistent with System Regulation 15.99.03, "Ethics in Research and Scholarship.
- 3.4.4 Cases that involve investigators not affiliated with a System component and which include the possibility of scientific or academic misconduct shall be processed in a manner consistent with their home institution's or organization's policies and procedures.
- 3.4.5 Appeals of impending sanctions for investigators shall follow normal System or component procedures. These may include a request for a hearing by the Committee on Academic Freedom, Responsibility and Tenure, as provided in the System Policy 12.01, Academic Freedom, Responsibility and Tenure.
- 3.4.6 Appeals of impending sanctions for investigators not affiliated with a System component shall follow the appeals process at their home institution or organization.

CONTACT FOR INTERPRETATION: Office of General Counsel

HISTORY: New (no previous APRM)