



OP 70.09: FINANCIAL CONFLICT OF INTEREST IN SPONSORED ACTIVITIES

PURPOSE

Faculty participation in outside professional or commercial activities generates important contributions to the University's core values, however it is essential to define and establish a mechanism to guard against the dangers of inappropriate participation. This policy serves to protect the integrity and objectivity of research by setting forth acceptable parameters relating to possible financial conflicts of interest which may arise from the outside professional or commercial activities of investigators.

This policy is designed to comply with the National Science Foundation's Investigator Disclosure Policy, 60 F.R. 132, pp. 35810-823 (July 11, 1995) and the U.S. Department of Health and Human Services' Objectivity in Research Rules, Subpart F - Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding Is Sought, 42 C.F.R. Part 50, Subpart F.

DEFINITIONS

The terms used in this policy statement are defined as follows:

- A. *Financial Conflict of Interest (FCOI)* - a significant financial interest that **could** directly and significantly affect the design, conduct, or reporting of research. The term "significantly" in this context means that the financial interest would have a material effect on the research.
- B. *FCOI Report* - the University's report of a financial conflict of interest to a Public Health Service (PHS) Awarding Component.
- C. *Financial Interest* - anything of monetary value, whether or not the value is readily ascertainable.
- D. *Institutional Responsibilities* - an investigator's professional responsibilities on behalf of the University, which may include for example (but not limited to): activities such as research, consultation, teaching, professional practice, institutional committee memberships, and service on committees such as the Institutional Review Board or the Institutional Animal Care and Use Committee.

- E. *Investigator* - the project director or principal investigator and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research, or proposed for such funding, which may include, for example, collaborators or consultants. Typically, students would not be considered “investigators” although there may be circumstances where, in the PI’s judgment, a student is working relatively autonomously and should be considered an investigator.
- F. *Manage* - taking action to address a financial conflict of interest, which can include reducing or eliminating the financial conflict of interest, to ensure, to the extent possible, that the design, conduct, and reporting of research will be free from bias.
- G. *PD/PI* - a project director or principal investigator of a research project.
- H. *PHS-supported Investigator* - includes those investigators currently funded by PHS and those seeking funding by a PHS Awarding Component.
- I. *Research* - a systematic investigation, study or experiment designed to develop or contribute to generalizable knowledge relating broadly to public health, including behavioral and social-sciences research. The term encompasses basic and applied research (e.g., a published article, book or book chapter) and product development (e.g., a diagnostic test or drug).
- J. *Senior/Key Personnel* – investigators who, although not the PI on the project, have independent responsibility for their contributions to the design, conduct and reporting of research. Key personnel are normally recorded as such in the grant application, progress report, or any other report submitted to the sponsor by the University. Key personnel on PHS proposals and grants must disclose their “Significant Financial Interests” to the University.
- K. *Significant Financial Interest* - a financial interest consisting of one or more of the following interests of the investigator (and those of the investigator’s spouse and dependent children) that reasonably appears to be related to a sponsored activity (or the investigator’s institutional responsibilities for PHS-supported investigators):
- 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, 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); or
 - Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.

- PHS-supported investigators also must disclose the occurrence of any reimbursed or sponsored travel (i.e., that which is paid on behalf of the investigator and not reimbursed to the investigator so that the exact monetary value may not be readily available), related to their institutional responsibilities.
 - Travel that is reimbursed or sponsored by a federal, state, or local government agency, an Institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education is not subject to this disclosure requirement.
 - The details of this disclosure, which will include:
 - Purpose of the trip
 - Identity of the sponsor/organizer
 - Destination, and
 - Duration

The term *significant financial interest* **does not include** the following types of financial interests:

- Salary, royalties, or other remuneration paid by the Institution to the investigator if the investigator is currently employed or otherwise appointed by the Institution, including:
 - Intellectual property rights assigned to the Institution and agreements to share in royalties related to such rights;
 - Any ownership interest in the Institution held by the investigator, if the Institution is a commercial or for-profit organization;
 - 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 as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education; or
 - Income from service on advisory committees or review panels for a federal, state, or local government agency, an Institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education.

L. *Research COI Manager* - the designated official with the responsibility to:

- Review all investigator disclosures of significant financial interests;
- Determine whether any significant financial interests relate to funded research;
- Determine whether a financial conflict of interest exists; and, if so,

- Submit the financial conflicts of interest to the Conflict of Interest Review committee to develop and implement a management plan that must specify the actions that have been, and must be, taken to manage such financial conflict of interest.
- Provide reports to sponsoring agencies as required.
- Maintain records relating to all investigator disclosures and the review of, and response to, such disclosures and all actions taken by MSU under this policy for a period of three years from the date the final expenditures report is submitted to the sponsor.
- Respond to written requests for information concerning any significant financial interest disclosed to the University in accordance with sponsor requirements.

POLICY/PROCEDURE

The University requires that investigators disclose any financial conflicts of interest related to the proposed research, or certify that no conflict exists, at the time of proposal submission. All conflicts of interest for each award must be managed prior to the expenditure of the award funds.

Because Mississippi law is more restrictive in its definition of a significant financial interest, employees are encouraged to disclose any financial interest at least annually and within thirty days of discovering or acquiring any new financial interest even if it does not meet the definition above of a significant financial interest. In addition, Mississippi law expands the scope of financial interests to those financial interests of an investigator's child or child's spouse, parent or parent's spouse, and sibling or sibling's spouse. See also HRM 60-416, Conflict of Interest/Ethics.

This policy applies to all university employees who serve as Investigators on sponsored activities and is in addition to any other policies, requirements, or laws pertaining to ethical standards of university employees. All financial conflicts of interest must be managed prior to the expenditure of funds on the project. Research activities for which Public Health Service (PHS) or National Science Foundation (NSF) funding is sought are subject to additional requirements outlined below under "Additional Sponsor Requirements".

Failure to make the necessary disclosure or follow an agreed upon management plan is a violation of this policy. Sanctions for non-compliance may include reprimands or other appropriate measures, up to and including termination.

CONFLICT OF INTEREST REVIEW COMMITTEE

The Conflict of Interest Review Committee (CIRC) serves the campus community by reviewing university research relationships for potential conflicts of interest. The committee is charged with ensuring that a researcher's personal interest in, or commitment to, entities outside the University's purview does not compromise or appear to compromise his/her objectivity in performing a research project, in mentoring students involved in a research project, or in

reporting the results of a research project conducted under the auspices of Mississippi State University.

The President, upon recommendation of the Vice President for Research and Economic Development and/or the Vice President for Agriculture, Forestry, and Veterinary Medicine, shall appoint a standing committee of 8 – 10 members that shall be carefully selected in order to minimize either the substance or the appearance of a personal or professional conflict of interest. The Committee shall have representatives from relevant areas across the University, including faculty, audit, research, legal, administrative, and compliance. Seeking to achieve a balance between industry/university collaborations and obligations to maintain the public trust, at least one representative on the Committee shall be persons from outside the university community. Term shall be for three years and shall be renewable.

The CIRC is not a punitive body. Its purpose is not to discourage industry/university partnerships, personal investments, or consulting, but to protect the integrity of the research related to these activities. The Committee will recommend action to the appropriate Vice President where the CIRC is unable to manage appropriately the conflict of interest.

ADDITIONAL SPONSOR REQUIREMENTS

Some sponsors, particularly governmental agencies such as NSF and PHS (PHS includes NIH, CDC, FDA, AHRQ, SAMHSA, HRSA, AoA, etc), 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 to the degree that they are more stringent shall prevail.

Each NSF-supported investigator, including senior/key personnel, must submit an Internal Approval Sheet (and Financial Interest Disclosure Form if necessary) prior to proposal submission.

Each PHS-supported investigator, including senior/key personnel, must disclose all significant financial interests (and those of the investigator's spouse and dependent children) that reasonably appear to be related to the investigator's institutional responsibilities:

- before any proposal for PHS-funded research is submitted;
- at least annually during the period of the PHS award;
- within 30 days of discovering or acquiring (e.g., through purchase, marriage, or inheritance) a new significant financial interest.

Each PHS-supported investigator must complete FCOI training related to the regulations and this policy prior to engaging in research related to any PHS-funded grant and at least every four years, and immediately under the designated circumstances:

- University policies change in a manner that affects investigator requirements;
- An investigator is new to the University;

- The University finds an investigator noncompliant with this policy or his/her management plan.

For all PHS-supported research projects at the University, the University will disclose financial conflicts of interest to the public in response to a written request received via US mail within five business days of a request for such information if (1) the significant financial interest was disclosed and is still held by the senior/key personnel; (2) the University has determined that the significant financial interest is related to the PHS-funded research; and (3) the University determined that the significant financial interest is a financial conflict of interest. All such requests must be specific to the investigator and project.

REVIEW

This OP will be reviewed as needed, but at least every four years, by the University Research Conflict of Interest Manager with recommendations for revisions presented jointly to the Vice President for Research and Economic Development and the Vice President of Agriculture, Forestry and Veterinary Medicine.

REVIEWED BY:

/s/ Judy Spencer
Chief Human Resources Officer

10/18/2016
Date

/s/ Judy Bonner
Provost and Executive Vice President

10/17/2016
Date

Gregory A. Bohach
Vice President for Agriculture, Forestry
and Veterinary Medicine

10/24/2016
Date

/s/ David R. Shaw
Vice President for Research and Economic
Development

10/15/2016
Date

/s/ Timothy N. Chamblee
Assistant Vice President and Director
Institutional Research and Effectiveness

10/25/2016
Date

/s/ Joan Lucas
General Counsel

11/01/2016
Date

APPROVED BY:

/s/ Mark Keenum
President

11/03/2016
Date