



Title: Policy on Conflicts of Interest and Commitment in Research
Effective Date: March 14, 2024
Issuing Authority: Provost
Policy Contact: Senior Vice Provost for Research
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Purpose

The National Institutes of Health (NIH) and the National Science Foundation (NSF) require grantees and investigators to comply with federal requirements that promote objectivity in research by establishing standards to ensure there is no reasonable expectation that the design, conduct, or reporting of research funded under Public Health Service (PHS) or NSF grants or cooperative agreements will be biased by any conflicting financial interest of an Investigator. The opportunity for investigators to receive financial or other personal rewards from their endeavors is not intrinsically unacceptable, as long as it does not adversely influence the objectivity, integrity, or professional commitment of an investigator. Hence, participation in a situation with opportunity for personal gain does not constitute an unacceptable situation in itself; it is the potential stimulus for unacceptable behavior that must be addressed. Accordingly, the objective of this policy is to provide guidelines that minimize the risk of unacceptable behavior in potential conflict situations, while facilitating and encouraging the full professional and personal development of faculty investigators through their research. Additionally, the policy ensures the integrity and objectivity of research and other scholarly activities of Mercer University employees through the disclosure and management of financial conflicts of interest.

Scope

This policy applies to all faculty of Mercer University.

Exclusions

None

Definitions

As used in this policy, the following terms have the meaning specified below:

Investigator: the principal investigator, co-investigator, and any other person (e.g., post-doctoral fellows) at Mercer University responsible for the design, conduct, or reporting of research or scholarly activities funded or proposed for funding by a sponsor.

PHS Awarding Component: the organizational unit of the PHS that funds the research.

Research: a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. The term encompasses basic and applied research and product development.

Responsible Representative of the Institution:

- Department Chair for faculty and other departmental personnel meeting the definition of investigator
- Dean for Department Chair
- Provost for Dean
- President for Provost and Senior Vice Presidents

Significant Financial Interest: anything of monetary value, including, but not limited to salary or other payments for services (e.g., consulting fees or honoraria); equity interest (e.g., stocks, stock options, or other ownership interest); and intellectual property rights (e.g., patents, trademarks, copyrights, and royalties from such rights). The term does not include:

- Salary, royalties, or other remuneration from Mercer University; and
- Income from seminars, lectures, or teaching engagements sponsored by public or nonprofit entities.
- Income from services on advisory committees or review panels for public or nonprofit entities; or
- An equity interest that, when aggregated for the investigator and the investigator's spouse and dependent children, 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% ownership in any single entity; or
- Salary, royalties, or other payments that, when aggregated for the investigator and the investigator's spouse and dependent children, are not expected to exceed \$10,000 during the next 12-month period.

Small Business Innovation Research (SBIR): a domestic small business concern engaging in Research/Research and Development (R/R&D) that has the potential for commercialization.

Policy Statement

A. Disclosure of Significant Financial Interest

1. Disclosure of Conflicts of Interest

Every investigator shall disclose any conflict of interest which arises during his/her employment to the appropriate responsible representative. This disclosure shall be on a "Significant Financial Interest Disclosure Form" (Disclosure Form). The Disclosure Form shall be signed by the investigator. A separate disclosure form is required for each project in which there is a (potential) conflict of interest. The investigator must submit a completed disclosure form to the appropriate Responsible Representative of the Institution prior to the time any research grant, contract, or other extramural proposal is submitted for review to the Office of Research Compliance. Investigators must certify that appropriate disclosures have been made and any potential conflicts of interest have been resolved. A certification is included on the Mercer University Office of Research Compliance "Proposal Transmittal Form" and must also be signed by the investigator. The disclosure shall be updated by the investigator at any time there is a change in the facts reported in the initial disclosure. If no conflict of interest existed at the time of the initial proposal, but such a conflict arises during the course of the project or proposal, the investigator shall file a Disclosure Form for the conflict of interest as soon as facts creating the conflict become known to him/her.

2. Resolution of Conflicts of Interest

- a. The Responsible Representative of the Institution to whom a disclosure of conflict of interest is made shall review such disclosure and make a determination as to whether or not a conflict of interest exists. The Senior Vice Provost for Research may provide assistance and guidance in the resolution and management of any conflicts. A conflict of interest will exist whenever the Responsible Representative of the Institution determines that a significant financial interest exists which could directly and significantly affect the design, conduct, or reporting of the research or scholarly activities funded or proposed for funding by a potential sponsor. Should a conflict of interest exist, the Responsible Representative of the Institution shall determine what restrictions, if any, should be imposed by Mercer University to manage, reduce, or eliminate such conflicts of interest.

By way of illustration, the following conditions or restrictions may be imposed to manage, reduce, or eliminate conflicts of interest:

- i. Public disclosure of significant financial interest;
- ii. Monitoring of research by independent reviewers;
- iii. Modification of the research plans;
- iv. Disqualification from participation in that portion of the research that would be affected by the significant financial interest;
- v. Divestiture of significant financial interests by the investigator; or
- vi. Severance of relationships that create actual or potential conflicts of interest.

In addition to the restrictions listed above, the Responsible Representative of the Institution shall have discretion to impose any other conditions or restrictions which, in their judgment, would manage, reduce, or eliminate any actual or potential conflict of interest and which would be consistent with applicable policies, regulations, and laws.

- b. Should the Responsible Representative of the Institution determine that Mercer University is unable to satisfactorily manage a conflict of interest, the Responsible Representative of the Institution shall immediately notify both the investigator and the Office of Research Compliance. The Office of Research Compliance shall be responsible for notifying the sponsor of Mercer University's determination.
- c. The President of Mercer University, either directly or through his/her designee, reserves the right to review all decisions regarding management and resolution of conflicts of interest made by a Responsible Representative of the Institution. In the event the President determines that the decision is incorrect, inappropriate, or inconsistent with applicable law, the President reserves the right to rescind, modify, or reverse a decision of the responsible representative.

3. Recording of Conflicts of Interest

All decisions made or taken by the Responsible Representative of the Institution shall be in writing and shall state the decision, the reasons therefore, and any conditions or restrictions imposed. This written decision, together with the written disclosure of conflict of interest, shall be maintained for at least three years after the latter of:

- a. The termination or completion of the award to which they relate; or
- b. The resolution of any government action involving those records.

4. Appeals

An employee who disagrees with a decision of a Responsible Representative of the Institution or other Mercer University official with respect to a conflict of interest which directly involves that employee may appeal such decision as follows:

- a. A decision of a department chair may be appealed to the Dean;
- b. A decision of a Dean may be appealed to the Provost;
- c. A decision of the Provost or Executive Vice President may be appealed to the President.

All appeals must be in writing and shall be submitted to the official hearing the appeal within five working days of the employee's notification of the decision. The decision of the President in all matters related to this policy shall be final.

5. Penalties

Any employee who violates this policy may be subject to disciplinary action up to and including dismissal.

B. Institutional Responsibilities

1. Certification

Mercer University must certify in each application to PHS or NSF for funding that:

- a. The institution has in effect a written and enforced process to identify and manage, reduce, or eliminate conflicting interests;
- b. Prior to expending any funds under the award, the Institution will report to the PHS Awarding Component the existence of a conflicting interest and assure that it has been managed, reduced, or eliminated, and, for any interest identified as conflicting subsequent to the Institution's initial report, a report will be made and the conflicting interest managed, reduced, or eliminated, at least on an interim basis, within 60 days; and
- c. Upon request, the Institution agrees to make information available to HHS regarding all conflicting interests and how those interests have been managed, reduced, or eliminated.

2. Non-Compliance

- a. If the failure of the Investigator to comply with Mercer University's policy has biased the research, Mercer University must promptly notify the PHS Awarding Component of the corrective action taken or to be taken.
- b. That Mercer University agrees to make information on conflicting interests available to HHS and NSF and how those interests have been managed, reduced, or eliminated; and
- c. If HHS determines that a PHS-funded project of clinical research, whose purpose was to evaluate the safety or effectiveness of a drug, medical device, or treatment, was designed, conducted, or reported by an investigator with a conflicting interest that was not disclosed or managed, Mercer University must require the Investigator(s) to disclose the conflicting interest in each public presentation of the results of the research.

Related Policies

This policy complies with Federal Regulation pertaining to sponsored research. For grants and cooperative agreements, the Public Health Service (PHS) Regulations are set forth in 42 CFR Part 50, subpart F section 50.601 through Section 50.607. For contracts, the PHS Regulations are set forth in 42 CFR Subpart 94, section 94.1 through Section 94.3 and Section 50.604

through Section 50.606. The National Science Foundation (NSF) Regulations are published in the Federal Register, Volume 60, No. 32, July 11, 1995, pages 35822-35823.

History

Revised July 31, 2023

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