

University Policy Number 4010

Subject: Financial Conflicts of Interest in Federally Funded Research

Responsible Parties: Vice President for Research and Economic Development, Office of Research Integrity & Assurance, Deans and Institute Directors, Provost, Office of Sponsored Programs

Procedures: [Introduction to Financial Conflict of Interest Policies](#)

Related University Policies: [Financial Conflicts of Interest in University Contracts with Business under Virginia Law](#), [Misconduct in Research and Scholarship](#), [Subrecipient Monitoring](#)

I. PURPOSE AND SCOPE

George Mason University (the institution or university) is committed to promoting objectivity in research and maintaining standards to ensure that the design, conduct, and reporting of research will not be biased by any conflicting financial interest of an investigator. This policy sets out the principles and processes that the institution employs in the service of these objectives pursuant to requirements for the receipt of Federal funds. 1

This policy applies to any person who is responsible for the design, conduct, or reporting of any research funded by a Federal agency.

II. DEFINITIONS

“Conflict of interest” means a set of facts that the Vice President for Research and Economic Development reasonably determines could result in a significant financial interest (SFI) directly and significantly affecting the design, conduct, or reporting of the federally funded research.

“Institutional Responsibilities” means an Investigator’s professional responsibilities on behalf of the Institution, and as defined by the Institution, including but not limited to, activities such as research, research consultation, teaching, professional practice, institutional committee memberships, and service on panels such as Institutional Review Boards and Safety Monitoring Boards and other responsibilities as defined by the institution.

“Investigator” means the Project Director/Principal Investigator (PD/PI) and any other person, regardless of title or position, who is independently responsible for the design, conduct or reporting of federally funded research. The Lead PD/PI on each project will identify all investigators. Questions regarding whether an individual is an investigator should be referred to the Office of Sponsored Programs for determination.

“Manage” means to take action to address a financial conflict of interest (FCOI), which can include reducing or eliminating the FCOI, to ensure, to the extent possible, that the design, conduct, and reporting of research will be free from bias.

“Senior/Key Personnel” means the PD/PI and any other person identified as Senior/Key Personnel by the Institution in the grant application, progress report, or any other report submitted to the funding agency by the institution.

“Significant Financial Interest” means: A financial interest consisting of one or more of the following interests of the Investigator (and/or those of the Investigator's spouse and dependent children) that reasonably appears to be related to the Investigator's institutional responsibilities:

- (i) With regard to any publicly traded entity, a SFI exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure certification and the value of any equity interest in the entity as of the date of disclosure certification, 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;
- (ii) With regard to any non-publicly traded entity, a SFI 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 (and/or the Investigator's spouse or dependent children) holds any equity interest (e.g., stock, stock option, or other ownership interest); or
- (iii) Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.

III. POLICY STATEMENT

A. Institutional commitments

The institution maintains and enforces this policy to promote objectivity in federally funded research that meets the requirements of the funding agency. The Office of Sponsored Programs informs each Investigator who participates in this research of the policy, the investigator's reporting responsibilities and applicable federal regulations.

Whenever the university conducts federally funded research through subrecipients, contractors or collaborators, it must take reasonable steps to ensure that investigators working for those entities meet the requirements of the funding agency, by providing the university with appropriate assurances, certifications, and reports of identified FCOI in a time period sufficient to enable reporting to federal agencies.

The Office of Sponsored Programs maintains records of all financial disclosures and all actions taken by the university with respect to each conflicting interest for at least three years

from the date of submission of the final expenditures report or other date required by the funding agency.

The university complies with federal regulations applicable to the funds it receives on matters governed by those regulations.

B. Disclosure requirements

Investigators who are planning to participate in any federally funded research must disclose certain financial interests related to that research. Specifically, each Investigator must provide a list of his or her known SFIs (and those of his or her spouse and/or dependent children) related to the investigator's institutional responsibilities.

As a part of the university's application for federal funds, each investigator must certify (1) that he or she has no such interests or (2) that he or she has such interests and has disclosed them through the institution's disclosure process. The Office of Sponsored Programs maintains custody of the Investigator's certification.

In addition, Investigators planning to participate in Public Health Service (PHS)-funded research are subject to additional requirements as detailed in the Appendix to this policy.

Certifications and any required disclosures must be provided prior to the university's submission of an application for federal funds. If the application results in the university's receipt of federal funds, each Investigator who participates in the funded research must update his or her certification and any required disclosure by June 30 of each year or more frequently if a new reportable significant financial interest is obtained. During this disclosure, Investigators must update the value of previously disclosed SFIs.

Investigators are not required to disclose the following:

- 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;
- 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 the federal, state, or local government agency, or 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.

C. Disclosure review process

Disclosures of SFIs related to institutional obligations are referred by the Office of Sponsored Programs to the Conflict of Interest Committee. This Committee is appointed by the Vice President for Research and Economic Development from among administrators, faculty, and Deans and Directors. In addition the Senior Vice President designates one member for appointment to the committee. The Committee reviews the disclosure and advises the Vice President for Research and Economic Development as to whether a financial conflict of interest related to federally funded research exists. If the Committee believes such a conflict exists, it also may recommend management strategies. The Vice President makes a final determination of whether a conflict of interest exists and notifies the Office of Sponsored Programs, the Investigator's Dean or Institute Director, or that individual's designee of this determination.

D. Managing conflicts of interest

If a conflict of interest related to federally funded research exists, the Conflict of Interest Committee, in cooperation with the Investigator, develops a management plan to ensure that the conflict is managed, reduced or eliminated and provides the recommended plan to the Vice President for Research and Economic Development. A management plan generally provides for compliance reviews at reasonable intervals. The Vice President and the Investigator agree to the management plan prior to the institution's expenditure of any funds under the award. If the investigator objects to a plan proposed by the Vice President, he or she may appeal the terms of the plan to the Provost, whose decision is final. The Office of Sponsored Programs maintains custody of the agreed-upon management plan and provides a copy of the plan to the Investigator's Dean or Institute Director or that individual's designee.

At a minimum, the management plan will describe the role and principal duties of the conflicted Investigator in the research project; conditions of the management plan; how the management plan is designed to safeguard objectivity in the research project; confirmation of the Investigator's agreement to the management plan through signature; how the management plan will be monitored to ensure Investigator compliance and other information as needed.

The Investigator's Dean or Institute Director or that individual's designee is responsible for monitoring the Investigator's compliance with the terms of the agreed-upon management plan. If the plan provides for periodic compliance reviews, the Dean, Institute Director or designee prepares a report of the review and sends a copy of the report to the Director of the Office of Sponsored Programs.

An investigator may agree to reduce or eliminate a financial conflict of interest prior to initiating federally funded research. If this occurs, the Conflict of Interest Committee may determine that a financial conflict of interest no longer exists and therefore does not require further management.

IV. RESPONSIBILITIES

Each federally funded investigator is responsible for accurate disclosure of financial

conflicts of interest. Deans and Institute Directors are responsible for ensuring management plans are appropriate and implemented as specified.

The division of Research and Economic Development is responsible for the overall administration of this policy including appointing the COI committee, receiving and reviewing disclosures, and maintaining records. The Provost is responsible for review of appeals and disciplinary actions under this policy.

V. COMPLIANCE

Failure to comply with this policy will result in the following consequences and may result in the imposition of other sanctions under established university procedures:

1. If an Investigator fails to provide a financial conflict of interest certification or fails to disclose a significant financial interest as required by Part II (B), the university does not submit the relevant application for federal funding or withdraws the application, as appropriate.
2. If an Investigator does not agree to an acceptable plan to manage, reduce, or eliminate a financial conflict of interest that is found to exist, as described in Part II (D), the university does not expend funds under the relevant award.
3. If an Investigator fails to disclose a reportable significant financial interest that creates a conflict requiring a management plan, the Investigator may be barred from participating in federally funded research for a period determined by the Vice President for Research and Economic Development, subject to the review of the Provost.
4. If an Investigator fails to comply with a material term of an approved management plan, the university may take any action relating to the award that is permitted by its terms and may pursue sanctions against the Investigator. In pursuing sanctions, the university applies the procedures comparable to an “investigation” and administrative actions in University Policy Number 4007 – Misconduct in Research and Scholarship.

VI. EFFECTIVE DATE, REVIEW AND APPROVAL

This policy is effective upon approval by the Provost and the Senior Vice President. The policy will be reviewed and, if necessary, revised annually or sooner if circumstances require. Any revision will take effect at the beginning of the first university fiscal year following its approval unless the revision specifies a different date.

Footnotes:

1 This policy is addition to and does not supersede the Virginia Conflict of Interests Act. sec. 2.2-3100 *et seq.*, Code of Virginia, as amended. ,2 See (1) for the Public Health Service, 42 CFR Part 50, Subpart F – Responsibility of Applicants for Promoting Objectivity in Research for Which PHS Funding Is Sought, and 45 CFR Part 94 – Responsible Prospective Contractors; and ((2) for the National Science Foundation, Investigator Financial Disclosure Policy, 60 Fed. Reg. 35820 (July 11, 1995); Grant Policy Manual 510 – Conflict of Interest Policies (July 1, 2005).

Approved:

Peter N. Stearns
Provost

Date:

Maurice W. Scherrens
Senior Vice President

Date:

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