

University Policy Number: 4XXX

Subject: Financial Conflicts of Interest in Federally-Funded Research

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

Procedures:

Related University Policies: University Policy Number 4001 -- Financial Conflicts of Interests in University Contracts with Businesses under Virginia Law, University Policy Number 4007 -- Misconduct in Research and Scholarship

I. PURPOSE AND SCOPE

George Mason University is committed to promoting objectivity in research and to 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 university employs in the service of these objectives pursuant to requirements for the receipt of Federal funds. The university also addresses these objectives under University Policy Number 4001 – Financial Conflicts of Interests in University Contracts with Businesses under Virginia Law.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. POLICY STATEMENT

A. University commitments

1. Maintain and enforce policy

The university maintains and enforces a policy to promote objectivity in Federally-funded research that meets the requirements of the funding agency. The university informs each investigator who participates in this research of the policy, the investigator's reporting responsibilities, and applicable Federal regulations.²

¹ This policy is addition to and does not supersede the Virginia Conflict of Interests Act on which University Policy Number 4001 is based. See 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).

2. Ensure compliance of collaborators

If the university carries out Federally-funded research through subgrantees, contractors, or collaborators, it takes reasonable steps to ensure that investigators working for those entities meet the requirements of the funding agency, by providing the university with appropriate assurances or certifications.

3. Retain records

The university 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.

4. Comply with Federal law

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 significant financial interests (and those of his or her spouse and dependent children) that meet either of the following tests:

- The significant financial interest would reasonably appear to be affected by the research, or
- The interest is in an entity whose financial interests would reasonably appear to be so affected.

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 will disclose them to the investigator's Dean or Institute Director or that officer's designee. The Office of Sponsored Programs maintains custody of the investigator's certification.

Certifications and any required disclosures must be provided prior to the university's submission of an application for funds from the Public Health Service or the National Science Foundation, and within 30 days of the university's submission of an application for other 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.

C. Disclosure review process

The investigator's Dean or Institute Director or that officer's designee reviews the investigator's disclosure. If that officer determines that a conflict of interest may exist, he or she refers the disclosure and his or her initial determination to a Conflict of Interest Committee appointed by the Vice President for Research and Economic Development from among administrators, faculty, and Deans and Directors. The officer notifies the Director of the Office of Sponsored Programs of the referral. The Committee reviews the disclosure and the initial determination and advises the Vice President as to whether that determination should be accepted. The Vice President determines whether a conflict of interest exists and notifies the Director of the Office of Sponsored Programs and the investigator's Dean or Institute Director or that officer's designee of this determination.

D. Managing, reducing, or eliminating conflicts of interest

If a conflict of interest 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 university'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 officer's designee.

The investigator's Dean or Institute Director or that officer'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, that officer prepares a report of the review and sends a copy of the report to the Director of the Office of Sponsored Programs.

III. 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 directly and significantly affecting the design, conduct, or reporting of the Federally-funded research.

"Investigator" means the principal investigator, any co-principal investigator, and any other person identified by a principal investigator as responsible for the design, conduct, or reporting of research.

“Significant financial interest” means anything of monetary value, including salary or other payments for services, equity interests, and intellectual property rights. The term does not include –

- Any remuneration from the entity or organization that applies for Federal funds;
- Any ownership interests in the entity or organization that applies for Federal funds under a Small Business Innovation Research (SBIR) Program;
- Income from seminars, lectures, or teaching engagements sponsored by public or nonprofit entities;
- Income from service on advisory committees or review panels for public or nonprofit entities;
- An equity interest (for the investigator and his or her spouse and dependent children in the aggregate) that both (1) does not exceed \$10,000 in value, as determined by public prices or other reasonable measures of fair market value, and (2) does not represent more than a five percent ownership interest in any single entity;
- Payments (for the investigator and his or her spouse and dependent children in the aggregate) that are not expected to exceed \$10,000 over the next twelve months.
- An interest in a diversified mutual fund that is so remote that it would not reasonably be expected to create a conflict of interest; and
- An asset, not known to the investigator, in a blind trust that is managed by an independent fiduciary.

IV. RESPONSIBILITIES

The Vice President for Research and Economic Development (Vice President) is responsible for the overall administration of this policy. Deans and Institute Directors or their designees, the Office of Sponsored Programs, and the Provost have certain responsibilities described in the 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 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 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, 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 for an “investigation” and administrative actions based on the findings of an investigation in University Policy Number 4007 – Misconduct in Research and Scholarship. Those procedures are incorporated into this policy *mutatis mutandis*.³

³ With the necessary changes.

VI. EFFECTIVE DATE, REVIEW, AND APPROVAL

This policy is effective upon approval by the Board of Visitors. The policy will be reviewed and, if necessary, revised every five years 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.

Approved:

Provost

Date: _____

Senior Vice President

Date: _____

Board of Visitors

Date: _____