

Policy 2203
Conflict of Interests Disclosure for Sponsored Programs

Date of Current Revision: January 2013

Primary Responsible Officer: Provost and Senior Vice President for Academic Affairs

1. PURPOSE

This policy is designed to protect the credibility and integrity of the university's faculty and staff so that public trust and confidence in the university's sponsored research and educational activities are ensured and to comply with federal guidelines concerning sponsored research. This policy establishes procedures and standards to ensure there is a reasonable expectation that the design, conduct or reporting of research funded under sponsored grants, contracts or cooperative agreements will be unbiased by any conflicting financial interests of an Investigator.

2. AUTHORITY

The Board of Visitors has been authorized by the Commonwealth of Virginia to govern James Madison University. See Code of Virginia section 23-164.6; 23-9.2:3. The Board has delegated the authority to manage the university to the president.

STATE OR FEDERAL STATUTE AND/OR REGULATION

In accordance with federal regulations, the university has a responsibility to manage, reduce or eliminate any actual or potential conflicts of interest that may be presented by the financial interests of an investigator. For grants from the National Institute of Health, see NIH Regulation, 42 CFR 50. For grants from the National Science Foundation, see NSF Grantee Standards (http://www.nsf.gov/pubs/policydocs/pappguide/nsf10_1/aag_4.jsp). University employees receiving sponsored funds must also comply with the policies of their sponsoring agencies. The university must comply with federal Office of Management and Budget circular OMB A-110 (2 CFR 215), which specifies that universities receiving federal funding must maintain a written and enforced policy on conflicts of interest.

This policy is in addition to and does not replace the Virginia State and Local Government Conflict of Interests Act (Code of Virginia, Section 2.2-3100) and the university's Conflict of Interests Policy (1106).

3. DEFINITIONS

Conflict of Interests:

A divergence between an individual's private interests and his or her professional obligations to the university such 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. An actual conflict of interests depends on the situation and the potential for the appearance of impropriety, and not necessarily on the character or actions of the individual.

Conflict of Interests Committee (COI Committee):

The university committee constituted for the purpose of determining what conditions or restrictions, if any, should be imposed by the university to manage actual or potential conflicts of interest arising from disclosed Significant Financial Interests as defined herein. The COI Committee is designed to ensure the integrity of the research performed by employees that operate within the institution. Committee members are appointed by the Provost and Senior Vice President of Academic Affairs.

The COI Committee shall contain, at a minimum, four faculty members representing a cross section of academic disciplines and the Director of the Office of Research Compliance.

Disclosure:

For this policy, disclosure means an investigator's disclosure of financial interests to the university related to his or her institutional responsibilities in research.

Financial Conflict of Interest:

A financial interest that is related to proposed university research (i.e., the interest reasonably appears to be affected by the research or is in an entity whose financial interest reasonably appears to be affected by the research) and that could directly and significantly affect the design, conduct or reporting of research.

Institutional responsibilities:

An investigator's professional responsibilities on behalf of the university which may include activities such as research, research consultation, teaching, clinical or other professional practices, institutional committee memberships, and service on panels such as an Institutional Review Board.

Investigator:

The principal investigator, project director, co-principal investigator or any other person at the university who is responsible for the design, conduct or reporting of research or educational activities funded, or proposed for funding, by an external sponsor. In this context, only for determining Significant Financial Interests, the term "Investigator" herein includes the investigator's spouse and dependent children.

Management Plan:

For this policy, an action plan to address a financial conflict of interests, which can include reducing or eliminating the financial conflict of interests to ensure, to the extent possible, that the design, conduct and reporting of research will be free from bias. The management plan shall meet the United States Department of Health and Human Services (HHS) Guidelines for Promoting Objectivity in Research. See 42 CFR Part 50, Subpart F, and 45 CFR Part 94. <http://grants.nih.gov/grants/policy/coifaq.htm>. For human subject research guidelines, see: <http://grants2.nih.gov/grants/policy/coi>

PHS Awarding Component:

The organizational unit of the Public Health Service (PHS) within HHS which funds research.

PHS Investigator:

An investigator who proposes or conducts PHS-funded research.

Research:

A systematic investigation, study or experiment designed to develop or contribute to generalizable knowledge. 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). The term includes but is not limited to any activity for which research funding is available from diverse funding agencies through a grant or cooperative agreement and authorized under statutory authority, such as a research grant, career development award, center grant, individual fellowship award, infrastructure award, institutional training grant, program project or research resources award.

Significant Financial Interests:

A "Significant Financial Interest" is any financial interest that has the potential to compromise an individual's objectivity. The dollar value that is considered "significant" for the purposes of this policy is determined by the relevant federal or state law or university policy. Funding agency applications

and guidelines contain dollar values specific to each situation. Significant Financial Interests include, but are not limited to:

- Salary or other payments for services, including consulting fees and honoraria, from any entity other than the university.
- Equity ownership or stock options. Excepted are equities held in retirement accounts or mutual funds.
- Sole proprietorship, partnership, ownership or membership as a partner or in a limited liability for-profit entity (includes remuneration from private consulting activities).
- Consulting substantially related to patented or patentable intellectual property in which the employee has an interest.
- Consulting for an entity that has a financial interest in or sponsors the employee's university scholarly activities.
- Ownership of, or rights held in, intellectual property or research materials (which may include rights to receive royalties), the value of which may be affected by the outcome of the employee's university activities. Excepted are intellectual property and research materials held by James Madison Innovations, Inc.
- Any of the above applicable to the employee's spouse and/or dependent children.

A financial conflict of interests (FCOI) exists under this policy when an investigator or member of his or her immediate family has a significant financial interest that could directly and significantly affect the design, conduct or reporting of research.

Subrecipient.

Another party who is assigned part of the obligations and tasks under a contract or an award.

4. APPLICABILITY

This policy applies to all JMU employees and all research and sponsored projects at JMU. The principles underlying disclosure and management, as described in this policy, are similar for a wide variety of types of conflict. However, because of the diversity of applicable federal and state laws and rules and funding agency policies, the precise mechanisms for disclosure and management may vary depending on the type of conflict and the applicable laws, rules and policies.

5. POLICY

The university requires that investigators disclose any significant financial interest that may present an actual or potential conflict of interests in relationship with research or a sponsored project requiring such disclosure. University employees receiving sponsored funds must also comply with the policies of their sponsoring agencies.

All JMU employees, prior to engaging in any research project, must complete appropriate training. This training must be repeated at least every four years. The training must be completed immediately if this policy is revised so as to affect the investigators' obligations, if an investigator is new to the university or if the university finds an investigator to have violated this policy or any applicable management plan. The training courses can be taken online at http://www.jmu.edu/sponsprog/research_compliance/conducttraining.html; see Financial Conflict of Interest. These courses, under the Collaborative Institutional Training Initiative (CITI), are titled "Responsible Conduct of Research (RCR)" and "Conflict of Interest" and encompass general research ethics as well as human and animal research standards.

The university will provide initial and ongoing reports of its management of financial conflicts of interests to external sponsors of university research as required and in accordance with this policy.

6. PROCEDURES

6.1 Required Disclosure: Prior to submission of a proposal or initiation of research, each investigator is required to disclose the following Significant Financial Interests to the university through the Office of Research Compliance:

- Any Significant Financial Interest of the investigator that would reasonably appear to be affected by the research or educational activities funded, or proposed for funding, by an external sponsor; or
- Any significant interest of the Investigator in an entity whose financial interests would reasonably appear to be directly and significantly affected by the research or educational activities funded, or proposed by funding, by an external sponsor.

6.1.1 Investigator Requirements. Investigators are required to complete training prior to engaging in research related to any funded grant or contract, and at least every four years thereafter, and immediately under designated circumstances:

- When the university's FCOI policies change in a manner that affects investigator requirements.
- When an investigator is new to the university.
- When the university finds an investigator noncompliant with its FCOI policy or management plan.

6.2 Updates to Disclosure. During the term of the outside sponsored research, the employee is required to annually update the disclosure. If any new Significant Financial Conflict of Interests arises during the term of the outside sponsored research, the employee must notify the Director of the Office of Research Compliance within 30 days so that any conflict resulting from the changed situation can be identified and reported, and appropriate measures taken to manage, reduce or eliminate it.

6.3 Discretionary Disclosure. Regardless of the above minimum requirements, a faculty or staff member, in his or her own best interest, may choose to disclose any other financial or related interest that could present an actual conflict of interests or be perceived to present a conflict of interests. Disclosure is a key factor in protecting an employee's reputation and career from potentially embarrassing or harmful allegations of misconduct.

6.4 Financial Conflict of Interest Form. The method of disclosing a potential conflict of Interests is the [Financial Conflict of Interest Disclosure Form](#) (DF), attached to this policy as Appendix A.

6.4.1. A DF will be required with each funding application.

6.4.2. Each Investigator shall complete a DF and attach all required supporting documentation. The completed DF must be submitted with the funding application and University Proposal Internal Approval Form (PIAF) to the Office of Research Compliance. Supporting documentation that identifies the business enterprise or entity involved and the nature and amount of the interest held by the employee should be submitted in a sealed envelope marked confidential and accompany the DF and the PIAF. Certain information must be enclosed:

1. Name of the entity with which the Investigator has a financial conflict of interests.
2. Nature of the financial conflict of interests (e.g., equity, consulting fees, travel reimbursement, honoraria).
3. Value of the financial interest or statement that a value cannot be readily determined.
4. A description of how the financial interest relates to funded research.

6.4.3. As required by federal regulation, all Significant Financial Interests must be disclosed prior to submission of a funding application or the university's execution of a cooperative agreement or sponsored research contract, any other funding agreement or prior to initiation of any human subjects research, whether funded or not. Each Investigator is required to submit a disclosure form describing any financial interests held by the investigator, the investigator's spouse or any dependent child of the investigator that the investigator determines to be reasonably related to the investigator's institutional responsibilities. All financial disclosures must be updated by investigators during the pendency of the award, either on an annual basis or as changes are made to previously reported Significant Financial Interests. If a new reportable Significant Financial Interest arises at any time during the period after the submission of the proposal through the entire period of any resulting award, the filing of a DF is also required.

6.5 Review of Disclosures. The Office of Research Compliance shall conduct an initial review of all financial disclosures prior to the investigator's expenditure of any funds, or prior to the initiation of the research in the case of research with no external funding, to determine whether a conflict of interests exists. A conflict of interests exists when the review reasonably determines that a Significant Financial Interest could directly and significantly affect the design, conduct or reporting of the proposed sponsored project, or could be perceived to do so.

6.6 Determination of Conflict. If a potential conflict of interests is determined to exist by the Director of the Office of Research Compliance, the disclosure will be referred to the university COI Committee. The investigator, in cooperation with the COI Committee, shall develop a management plan that details proposed steps that will be taken to manage, reduce or eliminate any actual or potential conflict of interests presented by a Significant Financial Interest. At a minimum the Management Plan shall address such issues as:

- Public disclosure of significant financial Interests by a written response to any requestor within five business days of a request, and a timely update of such information as requested;
- Review of research protocol by independent reviewers; and
- Monitoring of research by independent reviewers.

6.7 Conflict of Interests Committee (COI Committee). The specifics of financial interests and their relation to the proposed research activity may vary considerably. Therefore, it is not possible to guarantee that research may proceed under a management plan in any and all cases of financial conflicts of interest. In extreme situations, such as the involvement of investigators with significant financial interests in experiments with human participants, there will be a rebuttable presumption that such activities may not proceed.

If an appropriate management plan cannot be developed to achieve the goals of this policy, the COI Committee will determine what conditions or restrictions, if any, should be imposed by the university to manage actual or potential conflicts of Interests arising from disclosed Significant Financial Interests. These conditions or restrictions may include the following:

- Modification of the research plan;
- Disqualification from participation in all or a portion of the research funded;
- Divestiture of Significant Financial Interests; or
- Severance of relationships that create actual or potential conflict of interests.

6.8 Appeal of Decision. Should a faculty member wish to appeal a decision made by the COI Committee, he or she may present the appeal to the Provost and Senior Vice President for Academic Affairs, who will consider the case in consultation with the COI Committee.

6.9 Management directive. The approved management plan shall be incorporated into a memorandum 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 shall be signed by the investigator and the investigator's supervisor (usually an academic unit head). The memorandum shall be reviewed by the dean. Actual or potential conflicts of interests will be satisfactorily managed, reduced or eliminated in accordance with this policy prior to accepting any award, or they will be disclosed to the sponsoring agency for action.

6.10 Records. Records of Investigator financial disclosures and of actions taken to manage actual or potential conflicts of interests shall be retained by the Office of Research Compliance until three years after the termination or completion of the award to which they relate, or the resolution of any government action involving those records, whichever is later.

6.11 Violations of Policy. Whenever an Investigator has violated this policy or the terms of the memorandum, the COI Committee shall recommend sanctions to the Investigator's supervising university official.

6.12 Non-JMU Faculty and Staff. Collaborators from other institutions must comply with this policy. If federally-funded research will be carried out through a subrecipient (e.g., a subcontractor or consortium member):

1. the subrecipient shall certify in a written agreement that its research conflict of interests policy complies with the requirements of the applicable federal regulations, and that it will report any financial conflicts of interests of its investigators to the university by dates sufficient for timely reporting by the university to the federal agency; or
2. if it is unable to certify compliance, the subrecipient shall enter into a written agreement that provides legally enforceable terms requiring its investigators to report significant financial interests to the university pursuant to this policy and associated procedures.
3. The agreement must specify the time periods for the subrecipient to report identified financial conflicts of interest to the university. The time periods must be sufficient for the university to make any reports required by federal regulation.

6.13 Retrospective Review. The university is required to conduct a retrospective review in those cases of non-compliance with federal regulations but is not required to report the review to the awarding agency. The university is required to notify the awarding agency promptly and submit a report to the awarding agency only in cases where bias is found. The report will address the impact of the bias on the research project and the actions the institution has taken, or will take, to eliminate or mitigate the effect of the bias.

6.14 Responding to Public Requests for Information about PHS Funded Research. The university shall respond in writing within five business days to requests from the public for information about current financial conflicts of interest of senior/key personnel (the principal investigator or project director and any other person identified as senior/key in the PHS funding application or other reports to PHS) if such conflicts are related to PHS-funded research and are determined by the university to be Significant Financial Conflicts of Interests). The response will be made in writing, postmarked within five business days, and include the investigator's name, a description of the interest, and its dollar value range as required by the HHS regulations on Promoting Objectivity in Research.

7. RESPONSIBILITIES

Investigators have the responsibility to disclose any potential conflict of interests in any research or sponsored project on which they work.

The Director of the Office of Research Compliance has the responsibility to receive and initially review all DFs to determine whether a significant financial conflict of interests exists; determine whether they could directly and significantly affect the design, conduct or reporting of the research, creating a financial conflict of interests; work with the COI committee to implement a management plan to be approved by the university; monitor the plan; and make reports as required by the federal agency rules, policies and requirements.

Academic unit heads have the responsibility to sign off on an approved management plan that is incorporated into a memorandum 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.

Deans have the responsibility to review any such memoranda in their colleges.

The Provost and Senior Vice President for Academic Affairs has the responsibility to appoint members of the COI Committee and to hear any appeals from that committee's findings.

The COI Committee has the responsibility to determine what conditions or restrictions, if any, should be imposed by the university on an employee to manage actual or potential conflict of interests arising from disclosed Significant Financial Interests.

8. SANCTIONS

Investigators who fail to comply with the requirements of this policy or with a COI Committee management plan shall be subject to appropriate disciplinary action, up to and including termination of employment as provided in applicable university policies.

9. EXCLUSIONS

A Significant Financial Interest does not include the following:

- salary, royalties or other remuneration from the university;
- 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 that, when aggregated for the investigator and the investigator's spouse and dependent children, does not exceed \$5,000 in value as determined through reference to public prices or other reasonable measures of fair market value; or
- 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 not expected to exceed \$5,000.

10. INTERPRETATION

The authority to interpret this policy rests with the president and is generally delegated to the Provost and Senior Vice President for Academic Affairs.

Previous version: November 2003

Approved by the President: November 2003

Appendix A - [Significant Financial Interests Disclosure Form](#)