

Fitchburg State University
Financial Conflict of Interest Policy for
Sponsored Projects

A. Background

In accordance with Public Health Service (PHS) regulation 42 CFR Part 50, Subpart F *Responsibility of Applicants for Promoting Objectivity in Research* and consistent with the provisions of the National Science Foundation (NSF) NSF 60 FR 35820, Fitchburg State University has developed the following policy on financial conflict of interest (FCOI) for investigators applying to or holding grants from federal sponsors, including but not limited to, the National Institutes for Health and the National Science Foundation.

Since the initial promulgation of the PHS regulations in 1995, the issuance of a final rule to amend the regulations was issued in the Federal Register August 25, 2011. An institution applying for or receiving PHS funding from a grant, contract, or cooperative agreement must be in full compliance with the revised regulatory requirements. The regulation “promotes objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct and reporting of research funded under NIH grants or cooperative agreements will be free from bias resulting from investigator financial conflicts of interest.” Fitchburg State has developed this policy to protect the integrity of these programs and to comply with the revised federal regulations. It is the intent and policy of Fitchburg State as an institution of higher education in receipt of federal funds, to comply with present and future regulations. To that end, this policy is subject to further refinements as other rules are published.

Scope. The following statement of the policy applies to Fitchburg State University investigators or project directors applying to or holding grants from federal sponsors.

B. Applicability

Investigators submitting proposals for newly funded projects must ensure that all participants in the project who are responsible for the design, conduct, or reporting of the project submit the proper Financial Disclosure Statement to Fitchburg State Grant Center at the time of application. The investigator will submit an updated Financial Disclosure Statement annually and within fifteen (15) days of discovering or acquiring (e.g. through purchase, marriage, or inheritance) a new Significant Financial Interest.

Individuals who come to work on an established project through reallocation of effort, hiring, transfer, promotion, etc., and thereby become responsible for the design, conduct, or reporting of the project, must submit a Financial Disclosure Statement to the Fitchburg State Grant Center before beginning work on the project.

1. If the individual and his/her immediate family have no Significant Financial Interests related to the project, work may begin as soon as the null financial disclosure statement is submitted to Fitchburg State University Grant Center.
2. If Significant Financial Interests exist, the individual will delay work on the project

until the Vice President of Academic Affairs (see section E. Review of Disclosures, below) has reviewed and acted upon the information and the individual has agreed to abide by any conditions or restrictions imposed by the Vice President of Academic Affairs.

Collaborators, Subcontractors, Subrecipients, and visiting scientists must either comply with this policy or provide certification to Fitchburg State Grant Center that their institution is in compliance with pertinent Federal policies and that their portion of the project is in compliance with their institutional policies. Collaborators, Subcontractors, Subrecipients and visiting scientists, who rely on their institution's Financial Conflict of Interest Policy must report identified conflicts of interest to Fitchburg State within thirty (30) days to allow Fitchburg State to report the conflict to the Awarding Agency to meet reporting requirements.

C. Financial Disclosure

Any Fitchburg State University investigator responsible for the design, conduct, or reporting of research activities funded or proposed for funding by a federal funding agency and as overseen by Fitchburg State must reveal all Significant Financial Interests that relate to the project, and the investigator's institutional responsibilities (i.e. an investigator's professional responsibilities on behalf of Fitchburg State). In addition, such information must be disclosed for the investigator's immediate family, which is defined as his/her spouse or domestic partner and dependent children.

A Significant Financial Interest is defined as:

1. A financial interest consisting of one or more of the following interests of the investigator (and those of the investigator's spouse or domestic partner and dependent children) that reasonably appears to be related to the investigator's institutional responsibilities:

(a) 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;

(b) 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 domestic partner or dependent children) holds any equity interest (e.g., stock, stock option, or other ownership interest); or

(c) Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.

2. 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, provided, however, that this disclosure requirement does not apply to travel that is reimbursed or sponsored by excluded sources explained below.

A Significant Financial Interest does **not** include:

1. Salary royalties, or other remuneration paid by Fitchburg State to the investigator if the investigator is currently employed or otherwise appointed by Fitchburg State;
2. Intellectual Property Rights assigned to Fitchburg State and agreements to share in royalties related to such rights;
3. Funds and retirement accounts, as long as the investigator does not directly control the investment decisions made in these vehicles;
4. 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;
5. Income from service on advisory committees or review panels for a federal, state or local government agency, 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
6. Travel expenses that are 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.

D. Disclosure of Financial Interest Statements

All Financial Disclosure Statements and related documents are considered sensitive information and only those persons involved in the implementation of this policy will have access to such records.

Financial disclosures for federally funded projects will be made using the Fitchburg State Financial Disclosure Statement form. With this form investigators will either certify that they and their immediate family hold no Significant Financial Interest to the investigator's research and institutional responsibilities or indicate the existence of Significant Financial Interests and attach a full description and documentation.

Financial Disclosure Statements and any documentation should be submitted in a sealed envelope marked confidential to the Fitchburg State Grant Center. The Grant Center will inform Fitchburg State investigators of this requirement. Submission of the Financial Disclosure

Statement must be accomplished before a proposal for external funding will be endorsed and forwarded to a federal sponsor on behalf of Fitchburg State.

Investigators are responsible for updating their records of Significant Financial Interest annually during an award period so that accurate current information is on file with Fitchburg State at all times. Updated financial disclosure statements must be submitted to the Grant Center within fifteen (15) days of a change in the circumstances surrounding the investigator's Significant Financial Interests during the funded period of a project or while a proposal is pending.

E. Review of Disclosures

The general purpose of the review process is to help the investigator and Fitchburg State in avoiding threats to research or project integrity while protecting and furthering the research or project goals.

Before an award is accepted, the Vice President for Finance and Administration will review all disclosure statements that indicate the existence of Significant Financial Interests. He/She will refer the statement to the Vice President of Academic Affairs or his or her designee, as needed.

The Vice President of Academic Affairs (VPAA) will be responsible for determining whether or not an actual, potential, or apparent conflict of interest exists, i.e. whether the Significant Financial Interest of the investigator could directly and significantly affect the design, conduct, or reporting of the funded research. The VPAA may request additional clarifying information from the individual which will be treated as non-public information to the extent allowed by law. The VPAA may also solicit from investigators recommendations for conflict management plans.

If an updated Financial Disclosure Statement is submitted during the funded period of a project, the VPAA will review the new information within thirty (30) days of receipt to determine whether the changed circumstances pose an actual or apparent conflict and to decide what, if any, modification of the conflict management plan (see next section) should be made. Continued participation by the Investigator on the project is contingent upon certification to abide by any new conditions or restrictions imposed by the VPAA.

If an updated Financial Disclosure Statement is received during the time a proposal is pending, Fitchburg State will defer acceptance of the award until the VPAA has reviewed and acted upon the new information.

E. Management Plans for Conflict

If the VPAA determines that an actual, potential, or apparent Financial Conflict of Interest exists, it will recommend either refusal of the project or acceptance with the development and implementation of a management plan that may include, but are not limited to, the following:

1. Public disclosure of Significant Financial Interests;

2. Monitoring of the research by independent reviewers;
3. Disqualification from participation in all or part of the project;
4. Divestiture of Significant Financial Interests;
5. Severance of relationships creating conflict.

In all cases, resolution of the conflict or establishment of an acceptable management plan must be achieved within sixty (60) days of identification of a Financial Conflict of Interest subsequent to Fitchburg State's initial report under the award. Annual updates to the management plan will be completed for the duration of the project.

F. Appeals

Appeals of the VPAA's decision may be made to the Fitchburg State President, who will consult with the Investigator and the VPAA and make a final determination within thirty (30) days of the submission of the appeal.

G. Compliance

As part of the Financial Disclosure Statement, each Investigator must certify that if the VPAA determines that a conflict exists, the Investigator will adhere to all conditions or restrictions imposed upon the project and will cooperate fully within the individual(s) assigned to monitor compliance.

H. Enforcement

Failure to properly disclose Significant Financial Interests, or to adhere to conditions or restrictions imposed by the VPAA, will be considered a deviation from accepted standards of conducting research or projects at Fitchburg State University.

Alleged violations of this policy will be investigated by the VPAA, which will make recommendations for action to the President. Breaches of policy include failure to file the necessary disclosure statements; knowingly filing incomplete, erroneous or misleading disclosure forms; violation of federal guidelines; or failure to comply with procedures prescribed by the VPAA. If the President determines that the policy has been violated, he/she may impose sanctions including but not limited to notification of sponsor and termination of award; formal admonition; a letter to the investigator's personnel file; and suspension of the privilege to apply for external funding for a period of time determined by president.

Fitchburg State shall, within 120 days of the VPAA's determination of noncompliance, complete a retrospective review of the investigator's activities and the project to determine if there was bias in the design, conduct, or reporting of such research. Fitchburg State shall document the retrospective review and complete a mitigation report, in accordance with PHS regulations, if bias is found.

I. Records

The Fitchburg State University Grant Center will maintain records of all disclosures and associated activities securely and confidentially.

All records will be maintained for seven (7) years following termination or compliance of the projects or resolution of any government action involving the records.

A disclosure of an identified Financial Conflict of Interest (and associated required updates) for a federally funded research project at Fitchburg State University will be made publicly accessible, in accordance with the PHS regulations, via the reporting system that is required by the funding agency or by a written response to any requestor within five (5) business days of a request. The disclosure statement and associated information will not be released without notifying the investigator.

J. Training

Each investigator who is responsible for the design, conduct, or reporting of research activities in federally funded research projects at Fitchburg State must complete the approved Fitchburg State University training program prior to engaging in research or any expenditure of any funds related to any federally funded research grant or contract and at least every four (4) years thereafter.

An investigator shall complete the approved Fitchburg State training program within thirty (30) days under the following designated circumstances:

1. Fitchburg State Financial Conflict of Interest policy is changed in a manner that affects investigator requirements;
2. An investigator is new to Fitchburg State or to the research project; or
3. Fitchburg State finds an investigator noncompliant with this policy or management plan.

Fitchburg State University
Disclosure of Significant Financial Interest

(submitted pursuant to the requirements of the Fitchburg State University Financial Conflict of Interest policy)

Name: _____

I am reporting on activities: for the year _____

as an addendum to my most recent report

| | | |
|------------------------------|-----------------------------|--|
| <input type="checkbox"/> yes | <input type="checkbox"/> no | 1. Compensation (including travel expenses). Have you or a member of your Family received compensation from a for-profit entity for activities such as consulting, expert witness, advisory board membership, and the like? If yes, furnish information on an additional page and attach. |
| <input type="checkbox"/> yes | <input type="checkbox"/> no | 2. Equity. Do you or a member of your family own stock or hold stock options with a publicly-traded or privately-owned entity? If yes, furnish information on an additional page and attach. (see section C) |
| <input type="checkbox"/> yes | <input type="checkbox"/> no | 3. Role. Do you or a member of your family serve as a director, trustee, officer or other key employee in a for-profit corporation, partnership, business, or other entity outside of Fitchburg State University? If yes, furnish information on an additional page and attach. |
| <input type="checkbox"/> yes | <input type="checkbox"/> no | 4. Intellectual Property. Do you or a member of your family have rights to and/or receive royalties from intellectual property (including, patents copyrights and trademarks but excluding academic or scholarly works) licensed to and/or owned by a for-profit entity? Do NOT include intellectual property developed in relation to your role as faculty at Fitchburg State University. If yes, furnish information on an additional page and attach. |

Certification:

I have read and understand Fitchburg State University’s policy on Financial Conflict of Interest in externally Funded Projects and have completed this report to the best of knowledge and belief. If required, I will comply with any conditions or restrictions imposed by Fitchburg State University to manage any real or perceived conflicts. Should my outside financial or managerial interests, or those of my Family, change in a way that results in different answers to any of the questions asked in this report, I agree to submit a revision within fifteen (15) days of the change.

(date)

(signature)

additional page(s) attached

Addition to Financial Interests Report of: _____

Reporting for self family member:
name: _____
relationship: _____

Name of External Entity: _____
Address of External Entity: _____

Type of external relationship: (check all that apply)

| | |
|--------------------------|------------------------------|
| <input type="checkbox"/> | Consultant |
| <input type="checkbox"/> | Speaker |
| <input type="checkbox"/> | Advisory Board or Committee |
| <input type="checkbox"/> | Equity Holdings |
| <input type="checkbox"/> | Governing Board or Officer |
| <input type="checkbox"/> | Intellectual Property Rights |
| <input type="checkbox"/> | Royalty Income |
| <input type="checkbox"/> | Other (describe below) |

Amount of compensation or financial interest in reporting period: \$ _____

If travel paid by entity:

Destination _____

Amount \$ _____

Comments or explanatory information: