



Florida Agricultural and Mechanical University Board of Trustees Policy

Board of Trustees Policy Number:
2005-14

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Subject	Financial Conflict of Interest Governing Research
Authority	Responsibility of Applicants for Promoting Objectivity in Research for which Public Health Service Funding is Sought and Responsible Prospective Contractors; also known as the Financial Conflict of Interest, or FCOI, regulations (42 CFR Part 50 Subpart F and 45 CFR Part 94); Section 1004.28, and Chapter 112, Part III, Florida Statutes; FAMU Board of Trustees Regulations 1.019, 1.020 and 10.121.
Applicability	Research/educational activities which are performed, sponsored, or administered by Florida A&M University and is applicable to all FAMU employees and students who are investigators on sponsored projects at the University.

I. Policy Statement and Purpose

Research is an important and vital part of the mission of Florida A&M University (FAMU or University). The external sponsorship of research can result in the development of complex relationships between the University, its faculty, and staff, and the external sponsor(s) who support specific programs. To assure that research conducted under the auspices of the University is always of the highest integrity, and in response to federal government regulations, Florida A&M University has developed this policy on Financial Conflicts of Interest in Research and Other Sponsored Programs.

It is the policy of FAMU that any University employee (including the employee's spouse and dependent children) who is responsible for the design, conduct, or reporting of a sponsored project implemented by funds awarded to the University must disclose significant financial interests (i) that would reasonably appear to be affected by the research or educational activities funded or proposed for funding or (ii) in entities whose financial interests would reasonably appear to be affected by such activities.

II. Definitions

- A. Financial Conflict of Interest (FCOI)** - means a significant financial interest that could directly and significantly affect the design, conduct, or reporting of funded research. FCOI report means an institution's report of a financial conflict of interest to an Awarding Component.
- B. Financial Interest** – anything of monetary value, whether or not the value is readily ascertainable.
- C. Immediate Family** – refers to the researcher's parents, siblings, spouse, children and any equivalent relatives by marriage. It also refers to any individual who resides on a regular basis in the researcher's domicile or meets the definition of a related person as defined in FAMU Board of Trustees Regulation 10.121.
- D. Investigator** – the project director or principal investigator, - and any other person, regardless of title or position, who is responsible for the design, conduct, reporting of research funded or proposed for such funding, which may include, for example, collaborators or consultants. This definition includes Project Director/Principal Investigator (PD/PI).

- E. PD/PI** – means a project director or principal investigator of a funded research project; the PD/PI is included in the definitions of senior/key personnel and investigator.
- F. Research** – systematic investigation, study or experiment designed to develop or contribute to generalized knowledge relating broadly to public health, including behavioral and social sciences research. The term encompasses basic and applied research and product development and includes any such activity for which research funding is available from an Awarding Component through a grant or cooperative agreement.
- G. Researcher** - includes the principal investigator and all faculty and research staff members who will have responsibility for the design and conduct of the research as well as the dissemination of its results.
- H. Significant Financial Interest (SFI)** – refers to anything of monetary value, including, but not limited to, salary or other payments for services (e.g., consulting fees or honoraria); equity interests (e.g., stocks, stock options or other ownership interests); and intellectual property rights (e.g., patents, copyrights and royalties from such rights).

1. Inclusions:

- (i) Income (including salary) consulting payments; honoraria, reimbursement of expenses, royalty payments, dividends, or any other payment or consideration from a simple business entity, public entity, or non-profit entity exceeding \$5,000 during the prior twelve months;
- (ii) Equity (in the form of stock, stock options, real estate or any other investment of ownership interests) in any enterprise. (This does not apply in the case of stock holdings such as diversified or mutual funds where the investigator is unaware of specific stock held);
- (iii) In regards to a non-publicly traded entity, an 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 (or the investigator's spouse or dependent children) holds any equity interest;
- (iv) A position as director, officer, partner, trustee, or member of the board of directors of any business entity;
- (v) Income from seminars, lectures, or teaching engagements sponsored by public or nonprofit entities;
- (vi) Income from service on advisory committees or review panels for public or nonprofit entities; or
- (vii) Intellectual property interest on a patent filed or to be filed by a party other than the University.

2. Exclusions:

- (i) Income from seminars, lectures, or teaching engagements sponsored by and service on advisory or review panels for a federal, state or local government agency and institution of higher education;
- (ii) Academic teaching hospital, a medical center, or a research institute that is affiliated with institution of higher education;
- (iii) Income from investment vehicles, such as mutual funds and retirement accounts, as long as the investigator does not directly control investment decisions made in these vehicles;

- (iv) 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 \$5,000 in value as determined through reference to public prices or other reasonable measures to fair market value, and does not represent more than a 5% ownership interest in any single entity;
- (v) Salaries, royalties or other payments that, when aggregated for the investigator and the investigator's spouse and dependent children, are not expected to exceed \$5,000 during the next twelve month period; or
- (vi) Any ownership interests in the institution, if institution is an applicant under the Small Business Innovation Research Program or Small Business Technology Transfer Program.

I. Sponsored Research Project or Other Sponsored Program - includes a variety of possible activities and not research alone. Sponsored Programs can include curriculum development activity, public service projects, instrumentation and infrastructure awards, training grants, conference grants and any other activity funded either directly, or indirectly, by an agency of the federal government.

III. Investigator's Responsibility

Persons covered under this policy are expected to govern their professional activities in accordance with the University mission, regulations and with integrity. Covered persons are expected to identify and, when possible, avoid financial conflicts of interest. If a conflict cannot be avoided, the Statement of Financial Interests Form must be completed to allow for elimination or management of the financial conflicts.

In accordance with Section IV below covered persons must disclose any significant financial interest that involves themselves, spouse, and dependent children in organizations or companies whose financial interests may reasonably appear to affect or be affected by their sponsored activities.

IV. Disclosure of a Significant Financial Interest in Research

Florida A&M University investigators holding a significant financial interest as defined above must disclose this interest in writing **prior** to submission of a grant application or contract to the Office of Sponsored Programs or, for non-sponsored research, prior to initiation of the activity. The principal investigator must ensure that all investigators in the proposal disclose significant financial interests; however, each covered person is obligated to disclose real or apparent conflicts of interest. Covered persons shall disclose annually all significant financial conflicts which are covered under this policy. Covered persons shall also update their disclosure forms whenever a new significant financial interest has evolved, or when the existing interest ends or is materially altered, or if a new investigator with a significant financial interest is hired to work on the research project; that interest must be disclosed within 60 days. Disclosure should be made to the Division of Audit and Compliance. The research may not begin until the University has reviewed the disclosure and all parties have agreed to any necessary management strategies. Statement of Financial Interest Forms are available on the Division of Research website at www.famu.edu and click on RESEARCH. Disclosure documents shall be destroyed at the end of the retention period.

Investigators must also disclose the occurrence of any reimbursed or sponsored travel related to their institutional responsibilities: provided, however, that this disclosure requirement does not apply to travel that is reimbursed or sponsored by a federal, state, or local government agency, institution of higher education as defined in 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with FAMU. This disclosure, which will include, at a minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration.

V. Designated University Official

The Designated University Official is the university official designated by the President to complete the first level review of the investigator's Statement of Financial Interest Form and to determine if any reported interests reasonably appear to be affected by the project. The Designated University Official will be located in the Division of Audit and Compliance.

VI. Approvals/Responsibilities

If the University determines that such interest may affect the design, conduct, or reporting of the project, the University will take steps to manage or eliminate the conflict of interest. Records of financial disclosures and actions taken to manage conflicts of interest shall be retained at least three years beyond the termination or completion of the award to which they relate, or the resolution of any government action involving those records, whichever is longer.

It will be the responsibility of the Division of Research to file with the requisite Federal agency an inability of the University to satisfactorily manage a conflict of interest.

VII. Initial Report and Annual Report

A. The following information should be included in the report:

1. Grant/Contract number;
2. Project Director/Principal Investigator (PD/PI) or Contact PD/PI;
3. Name of Investigator with FCOI;
4. Whether FCOI was managed, reduced, or eliminated;
5. Name of the entity with which the Investigator has a FCOI;
6. Nature of FCOI, e.g., equity, consulting fees, travel reimbursement, honoraria;
7. Value of the financial interest \$0-4,999; \$5K-9,999; \$10K-19,999; amounts between \$20K-\$100K by increments of \$20K; amounts above \$100K by increments of \$50K or statement that a value cannot be readily determined;
8. A description of how the financial interest relates to a funded research and the basis for the Institution's determination that the financial interest conflicts with such research;
9. Key elements of the Institution's management plan;
10. ANNUAL REPORT;
11. Status of the FCOI; and
12. Changes to the management plan.

B. The following information will be included in an annual report:

1. Status of the FCOI
2. Changes in the Management Plan

VIII. Review and Appeal Process

When a conflict of interest is declared, the Statement of Financial Interests Form should be submitted to the Division of Audit and Compliance. If a potential conflict of interest is identified in the initial review, the Disclosure material will be reviewed by the Conflict of Interest Committee (COIC), a standing committee appointed by the Vice President for Sponsored Research and managed by the Office of Animal Welfare and Research Integrity. The COIC will offer recommendations for compliance to the principal investigator within sixty (60) days.

The principal investigator may appeal the decision of the COIC to the Vice President for Research and, ultimately, to the President of the University if the recommendations are deemed to be unjustified.

IX. Management of Conflicts of Interest

- A.** An investigator has a conflict of interest when the COIC reasonably determines that a significant financial interest could directly and significantly affect the design, conduct, or reporting of sponsored research/educational activities. In such circumstances, the COIC may recommend that the proposal shall not be submitted for funding (or terminated, if funded prior to the development of a conflict). In situations where reasonable doubt may exist about the conflict of interest, certain conditions or restrictions may be imposed. These may include, but are not limited to:
1. public disclosure of significant financial interests(e.g., when presenting or publishing the research);
 2. for research projects involving human subjects research, disclosure of financial conflicts of interest directly to participants;
 3. monitoring of research by independent reviewers;
 4. modification of research plan;
 5. change of personnel or personnel responsibilities or disqualification from participation in the portion of the funded research/education that would be affected by the significant financial interest;
 6. divestiture of significant financial interest(s) (e.g., sale of an equity interest); or
 7. severance of relationships that create conflicts.

If the COIC determines that imposing conditions or restrictions would either be ineffective or inequitable, and that the potential negative impact that may arise from a significant financial interest are outweighed by interest of scientific progress; technology transfer, or the public health and welfare, then the COIC may allow the research/educational activity to go forward without imposing such conditions or restrictions.

- B.** Process when FAMU Untimely Identifies a Significant Financial Interest – there are two specific occasions and requirements concerning the untimely discovery of a significant financial interest.
1. Whenever FAMU identifies a significant financial interest that was not disclosed timely by an Investigator or, for whatever reason, was not previously reviewed by FAMU during an ongoing funded research project, the designated official(s) shall, within sixty (60) days:
 - (i) review the significant financial interest;
 - (ii) determine whether it is related to funded research;
 - (iii) determine whether a financial conflict of interest exists; and, if so
 - (iv) implement, on at least an interim basis, a management plan that shall specify the actions that have been, and will be taken to manage such financial conflict of interest going forward.
 2. In addition, whenever a financial conflict of interest is not identified or managed in a timely manner including:
 - (i) failure by the Investigator to disclose a significant financial interest;
 - (ii) failure by FAMU to review or manage such a financial conflict of interest; or
 - (iii) failure by the investigator to comply with a financial conflict of interest management plan.

FAMU shall, within 120 days of the Institution's determination of noncompliance, complete a retrospective review of the investigator's activities and the funded research project to determine whether any funded research, or portion thereof was biased in the design, conduct, or reporting of such research.

X. Public Accessibility to Information of Conflict of Interest

FAMU must make certain information available concerning identified FCOIs held by senior/key personnel via a publicly accessible web site or by a written response to any requestor within five business days of a request, and update such information as specified in the rule.

Information concerning any significant financial interest disclosed to FAMU that is still held by the senior/key personnel, that is related to the funded research, and that is determined to be a financial conflict of interest will be available on the Division of Research website at www.famu.edu and click on RESEARCH. This website is to be updated annually. The information will also be made available as a written response to any requestor within five business days of a request. The information shall include: Investigator's name; the Investigator's title and role with respect to the research project; the name of the entity in which the significant financial interest is held; the nature of the significant financial interest; and the approximate dollar value of the significant financial interest, or a statement that the interest is one whose value cannot be readily determined through reference to public prices or other reasonable measures of fair market value.

The website must be updated at least annually and within 60 days of the discovery of a new financial conflict of interest. The information concerning the significant financial interests of an individual disclosed via the website or through a written request shall remain available for at least three years from the date that the information was most recently updated.

XI. Retrospective Review

FAMU is required to conduct a retrospective review in those cases of non-compliance with the regulation but is not required to report the review to the Awarding Component. FAMU will be required to notify the Awarding Component promptly and submit a report to the Awarding Component only in cases where bias is found. The report will address the impact of the bias on the research project and the actions FAMU has taken, or will take, to eliminate or mitigate the effect of the bias.

Retrospective Review –FAMU is required to document the retrospective review; such documentation shall include, but not necessarily be limited to, all of the following key elements:

1. Project number;
2. Project title;
3. PD/PI or contact PD/PI if a multiple PD/PI model is used;
4. Name of the Investigator with the FCOI;
5. Name of the entity with which the Investigator has a financial conflict of interest;
6. Reason(s) for the retrospective review;
7. Detailed methodology used for the retrospective review (e.g., methodology of the review process, composition of the review panel, documents reviewed);
8. Findings of the review; and
9. Conclusions of the review.

Based on the results of the retrospective review, if appropriate, the Vice President for Research shall update the previously submitted FCOI report, specifying the actions that will be taken to manage the financial conflict of interest going forward. If bias is found, the Vice President for Research is required to notify the Awarding Component promptly and submit a mitigation report to the Awarding Component. The mitigation report must include, at a minimum, the key elements documented in the retrospective review above and a description of the impact of the bias on the research project and the Institution's plan of action or actions taken to eliminate or mitigate the effect of the bias (e.g., impact on the research project; extent of harm done, including any qualitative and quantitative data to support any actual or future harm; analysis of

whether the research project is salvageable). Thereafter, the Vice President for Research will submit FCOI reports annually, as specified elsewhere in this subpart. Depending on the nature of the financial conflict of interest, the COIC may determine that additional interim measures are necessary with regard to the Investigator's participation in the funded research project between the date that the financial conflict of interest or the investigator's noncompliance is determined and the completion of the Institution's retrospective review.

XII. Investigator Training

Each Investigator must complete training prior to engaging in research related to any grant or contract and at least every four years, and immediately under the designated circumstances :

1. FAMU FCOI policies change in a manner that affects Investigator requirements;
2. An Investigator is new to FAMU; and
3. FAMU finds an Investigator noncompliant with FAMU's FCOI policy or management plan.

XIII. Sanctions

Failure to file a complete Statement of Financial Interest for a sponsored project, or adhere to the guidelines developed by the COIC will be grounds for disciplinary action under applicable University regulations and collective bargaining agreements. In addition, sponsors may terminate current awards and/or contracts and may determine an investigator ineligible to receive future awards if university policy is violated.