



FLORIDA AGRICULTURAL AND MECHANICAL UNIVERSITY
Board of Trustees Policy

Board of Trustees Policy Number:
2005-14

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Subject	Financial and Other Conflicts of Interest and Commitment 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); DOE O 486.1 (6-13-2019); DOE O 142.3B; Uniform Guidance 2 CFR §200.112 Conflict of Interest and §200.113 Mandatory Disclosures ; Section 1004.28, F.S. 1012.977 and Chapter 112, Part III, Florida Statutes; and University Regulations 1.019, 1.020, 10.121, and 10.122.
Applicability	Applicable to all Florida A&M University faculty, staff, students, and affiliates engaged in domestic and foreign research/academic activities. This Policy also applies to individuals whose research/academic activities are performed, sponsored, or administered by Florida A&M University. These individuals are referred to collectively as “University Personnel.”

I. Policy Statement and Purpose

Research is an important and vital part of the mission of Florida A&M University (University). The external sponsorship of research or similar commitments 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, while being responsive to federal government regulations and other agencies (public or private), the University has developed this Policy on Financial and Other Conflicts of Interest and Commitments Governing Research.

Any University Personnel (including the individual’s immediate family) who is responsible for the design, conduct, or reporting of a research project/academic activity, regardless of whether such project is sponsored or implemented by funds awarded to the University, must disclose any commitment or significant financial interest:

- that may reasonably appear to affect the research or academic activities funded or proposed for funding, or
- in entities whose financial interests and commitment would reasonably appear to be affected by such activities.

II. Definitions

- A. **Affiliates:** A compensated or uncompensated subcontractor, sub-recipient, consultant, or other third-party entity performing research services for the University under a written or verbal agreement.
- B. **Awarding Component:** The organizational unit of the agency that funds the research.
- C. **Conflict of Commitment:** Occurs when University Personnel engage in an Outside Activity, either paid or unpaid, that could interfere with their professional obligations to the University.
- D. **Conflict of Interest (COI):** Occurs when University Personnel's financial, professional, commercial or personal interests or activities outside of the University affects, or appears to affect, their professional judgement or obligations to the University.
- E. **Designated University Division:** The University President or designee shall assign the appropriate Division responsible for processes implicating sponsored research and all other research/academic activities under this policy.
- F. **Disclosure:** To provide relevant information about an individual's external commitments and financial interests to parties inside and outside the University to assure full awareness of potential conflicts and institutional efforts to address them. Disclosure must be sufficiently detailed, timely, accurate and not false, erroneous, misleading or incomplete.
- G. **Educational Activities:** Activities of educating or instructing that impart knowledge or skills.
- H. **Entity:** Any business, company, or other organization, whether public or private, domestic or foreign, including without limitation any partnership, corporation, limited liability corporation, unincorporated association, or other institution or organization, whether for-profit or not-for-profit.
- I. **Financial Conflict of Interest (FCOI):** A Significant Financial Interest that could directly and significantly affect the design, conduct, or reporting of funded research or activities.
- J. **Financial Conflict of Interest Report:** An institution's report of a financial conflict of interest to an Awarding Component.
- K. **Financial Interest:** Anything of monetary value, other than that provided by the University, whether the value is readily ascertainable, including interests received from domestic and foreign entities.
- L. **Foreign Country of Concern:** Countries identified by Federal and State government to which particular consideration is given for policy reasons and may be subject to travel or other safety restrictions. Countries may appear on the sensitive country list for reasons including national security, nuclear nonproliferation, regional instability, threat to national economic security and/or terrorism support.
- M. **Foreign Entity:** Includes, but is not limited to, governments, universities, individuals, and public or private companies or organizations that are formed or based outside of the United States.
- N. **Foreign Talent Recruitment Program:** Any foreign state sponsored attempt to acquire U.S. funded scientific research through recruitment programs that target scientists,

engineers, academics, researchers, and entrepreneurs of all nationalities working or educated in the United States.¹

- O. **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.
- P. **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.
- Q. **Outside activity:** Includes anything University Personnel does for an entity or an individual, other than the University, that related to the University Personnel's expertise.
- R. **Other Support:** Any and *all* resources and affiliations made available to University Personnel in support of and/or related to all of their research endeavors, regardless of whether they have monetary value and regardless of whether they are based at the institution and the University Personnel identifies for the current grant. This may include:
 - 1. in-kind resources,
 - 2. financial support through grants, contracts, and other awards,
 - 3. positions and scientific appointments,
 - 4. selection to "talents" or similar-type programs, and
 - 5. "gifts" where items or funds are received with conditions attached or deliverables expected in return.
- S. **Project Director/Principal Investigator (PD/PI):** A person designated as a project director or principal Investigator of a funded research project.
- T. **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 research, applied research, and product development. This also includes any such activity for which research funding is available from a funding source through a grant or cooperative agreement.
- U. **Researcher:** Includes the PD/PI and all faculty and research staff members who will have responsibility for the design, conduct of the research, and as the dissemination of its results.
- V. **Significant Financial Interest (SFI):** Refers to anything of monetary value exceeding \$5,000, 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); any other support, and intellectual property rights (e.g., patents, copyrights and royalties from such rights) reasonably related to the University Personnel's institutional responsibilities.

¹ US Department of Energy, "DEPARTMENT OF ENERGY FOREIGN GOVERNMENT TALENT RECRUITMENT PROGRAMS," DOE O 486.1 (6-7-2019)

W. Sponsored Research Project or Other Sponsored Program: Includes a variety of possible activities and not research alone. Sponsored Programs can include cooperative agreements, 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 or other agencies as designated in the terms and conditions of the award.

X. University Personnel: Florida A&M University faculty, staff, students, and affiliates engaged in domestic and foreign research/academic activities.

III. University Personnel's Responsibility

University Personnel are expected to govern their professional activities in accordance with the University mission, regulations, and with integrity. University Personnel are expected to identify and, when possible, avoid all conflicts of interest and commitment, including financial. If a conflict cannot be avoided, the disclosure form must be completed to allow for elimination or management of conflicts.

In accordance with this Policy, University personnel, as defined above, must disclose any conflicts of interest or commitment, including significant financial and commitment conflicts of interest that involve themselves and immediate family in organizations or companies whose financial interests may reasonably appear to affect or be affected by their sponsored activities.

IV. Foreign Talent Recruitment Programs

University Personnel are restricted from participating in foreign talent recruitment programs that endeavor to promote the language or culture of a foreign country of concern identified by appropriate Federal or State agencies. University Personnel may engage in other international researcher activities allowable by federal law or agency regulations, and subject to disclosure.

V. Intellectual Property

The University is committed to the advancement of research and innovation in the development of intellectual property, to include patents, copyrights, trademarks and other proprietary methodologies.

The University, therefore, must protect real and perceived disclosure of intellectual property to entities in which University inventors have personal or financial interests or are adverse to the University's interest. The U.S. recognize the value of scientific collaboration with foreign organizations, but exploitation of the openness of the U.S. scientific community threatens U.S. national interests. University Personnel must be responsible stewards of U.S. taxpayer money and to prevent funded research or academic activities from inappropriately benefiting foreign competitors. More information, including applicable definitions, ownership and intellectual rights are located in the University Regulation 10.128.

VI. Foreign Influence

This Policy covers conflicts of interest or commitment related to foreign entities as well, regardless of compensation. University Personnel have a conflict of interest when that interest could directly and significantly affect or threaten the United States by facilitating the unauthorized transfer of technology and intellectual property to foreign governments.

A. COIs, as defined above, include, but are not limited to:

- A. Participating in any Foreign Talent Recruitment Program.
- B. Traveling outside the U.S. and hosting international scholars, both short- and long-term.
- C. Failure to report all research support, including foreign support at the proposal stage and in progress reports.
- D. Participating in any academic, research, or administrative appointments at a foreign institution, even if the appointment is uncompensated. This includes appointments that are full-time, part-time, honorary, adjunct, or voluntary.
- E. Any engagement in agreement with a foreign university for which the University Personnel directs non-University students, postdocs, or other personnel affiliated with that foreign university.
- F. Any foreign affiliation that is included in any publication by the University Personnel.
- G. Any non-University agreement in which foreign funds or other resources are provided to University Personnel for activities either at the University or at a foreign institution.
- H. Any agreement or relationship that assigns intellectual property (IP) rights to the foreign institution.
- I. Any agreement or relationship with a foreign entity in which the University Personnel receives payments for salary, stipends, or living expenses.
- J. Holding a position such as founder, partner, employee, or board member at a company, non-profit, governmental agency, or other foreign entity.
- K. Receiving living/lodging funds or reimbursements or other remunerations.
- L. Having significant ownership interest in a foreign company related to the University Personnel's role/responsibility.
- M. Financial interests in a foreign entity that does business with or competes with the University (including seeking research funding).
- N. Receiving travel funds or reimbursements from a foreign entity.
- O. Receiving an honorarium from a foreign entity.
- P. Sharing proposals, applications, or meeting materials with a foreign entity.
- Q. Failure to disclose foreign financial and Commitment Conflicts of interest during grant application, Just in-Time or award.
- R. Failure to disclose foreign other affiliations or positions that comes with resources, whether financial or in-kind.

VII. Types of Conflict (Conflicts of Interest/Conflict of Commitment/Significant Financial Interest)

University Personnel must be cognizant of all types of conflict of interest, including conflicts of commitment and significant financial conflict of interest. University Personnel shall disclose any such conflict using the appropriate process outlined herein and related University regulations.

A. University Conflict of Interest/Conflict of Commitment

The responsibility of University Personnel is the full and competent performance of all duties pertinent to his/her relationship with the University. Outside employment/activities or financial interests which interferes with the University Personnel's obligations to the University are prohibited. University Personnel should avoid actual or apparent conflicts of interest or commitment between University obligations and outside employment/activities or financial interests.

B. Financial Conflict of Interest (FCOI)

University Personnel have a significant financial interest (SFI) when that interest could directly and significantly affect the design, conduct, or reporting of funded research or activities.

1. Examples of such inclusions include, but are not limited to:

- A. 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;
- B. 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;
- C. Regarding 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 immediate family member) holds any equity interest;
- D. A position as director, officer, partner, trustee, or member of the board of directors of any entity;
- E. Income from seminars, lectures, or teaching engagements sponsored by public or nonprofit entities;
- F. Income from service on advisory committees or review panels for public or nonprofit entities; or
- G. Intellectual property interest on a patent filed or to be filed by a party other than the University.

2. Examples of FCOI may not include the following; however, these interests may implicate other conflict areas identified in this policy:

- A. 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;
- B. Income from an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education;
- C. Income from investment vehicles, such as mutual funds and retirement accounts, as long as the PI does not directly control investment decisions made in these vehicles;
- D. An equity interest that, when aggregated for the PI, spouse, or 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;
- E. Salaries, royalties or other payments that, when aggregated for the PI and the PI's spouse and dependent children, are not expected to exceed \$5,000 during the next twelve-month period; or
- F. Any ownership interests in the institution, if institution is an applicant under the Small Business Innovation Research Program or Small Business Technology Transfer Program.

VIII. Disclosure Requirements

All University Personnel are responsible for the annual disclosure of University conflict of interest/commitments outlined in part A of this section. Applicable University Personnel must also complete conflict of interest disclosures as outlined in part B of this section. University Personnel are required to make the appropriate disclosures annually, or upon the occurrence of a change in circumstance:

A. Conflict of Interest/Commitment

In addition to annual disclosure, University Personnel who propose to engage in any outside employment/activity must report, in writing, to the President or President's designee via the individual's supervisor as soon as practicable in advance of such employment/activity.

B. Financial Conflict of Interest

University Personnel applying for sponsored research or Institutional Review Board (IRB) approval must complete the project specific disclosure with each proposal. University Personnel 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 Designated University Division prior to initiation of the activity. Principal investigators 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. University Personnel shall disclose annually all financial conflicts covered under this policy.

The research may not begin until the University has reviewed the disclosure and all parties have agreed to any necessary management strategies. Disclosure documents shall be maintained for the appropriate retention period.

C. Updating Disclosures Due to Changes in Circumstances

1. University Personnel shall also update their disclosure within fourteen (14) calendar days in the event of a change in circumstances. Such changes include, but are not limited to the following instances:
 - a. A new significant financial interest has evolved or occurred;
 - b. The existing interest ends or is materially altered; or
 - c. A new investigator/personnel with a significant financial interest is hired to work on the research project.

IX. Conflict of Interest/Financial Conflict of Interest Review Processes

A. Conflict of Interest/Commitment Review Process

1. When the University identifies a conflict of interest related to University Personnel, the University may, at its sole discretion, prohibit the individual from engaging in any activity presenting a potential conflict; limit the employment/activity; or implement other measures the University deems reasonably necessary to eliminate the potential conflict.

B. Financial Conflict of Interest Review Process

1. Preliminary Review

University Personnel will submit annual conflict of interest disclosures to the Designated University Division to perform a preliminary review for accuracy and completeness.

2. First Level Review: Designated University Official

The Designated University Official is the University official designated by the President to complete the first level review of the disclosure form and to determine if any reported interests reasonably appear to affect the integrity of the University. The Office of Compliance and Ethics serves as the Designated University Official for this review, working in collaboration with the Office of Animal Welfare and Research Integrity.

3. Initial Report and Annual Report

Upon receipt of a conflict of interest disclosure, Designated University Division(s) must prepare an initial report that is updated at least annually. The following information should be included in the initial report:

- a. Sponsoring agency(ies);
- b. Grant/Contract number;
- c. Funding performance period;
- d. University assigned project number if awarded;
- e. Project Director/Principal Investigator (PD/PI) or Contact PD/PI;

- f. Name of Investigator with FCOI;
- g. Whether FCOI was managed, reduced, or eliminated;
- h. Name of the entity with which the Investigator has a FCOI;
- i. Nature of FCOI, e.g., equity, consulting fees, travel reimbursement, honoraria;
- j. 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;
- k. A description of how financial interest relates to a funded research and the basis for the Institution's determination that a financial interest conflicts with such research;
- l. Key elements of the Institution's management plan;
- m. The following information will be included in an annual report;
- n. Status of the FCOI; and
- o. Changes in the Management Plan.

4. Review and Appeal Process

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 Designated University Division and managed by the Office of Animal Welfare and Research Integrity. The COIC will provide findings and offer recommendations for compliance actions to the Designated University Division Vice President and the University Personnel within fourteen (14) days.

University Personnel may appeal the decision of the COIC to the Designated Division Vice President and, ultimately, to the President of the University if the recommendations are deemed to be unjustified. The President's decision is final.

X. Public Accessibility to Information of Conflict of Interest

- A. When the COIC determines a significant financial conflict of interest exists and continues, the University will ensure the following information is publicly accessible by a written response within five business days of a request:
- 1. The researcher's name, title, and research project role,
 - 2. The name of the entity in which the significant financial interest is held,
 - 3. The nature of the significant financial interest, and
 - 4. The approximate dollar value of the significant financial interest (within dollar ranges) or a statement that a value cannot be readily determined. through reference to public prices or other reasonable measures of fair market value.

XI. Financial Conflict of Interest Retrospective Review

- A. The University is required to conduct a retrospective review in cases of non-compliance with the regulation. Reports to the Awarding Component will address the impact of the

bias on the research project and what actions the University has taken, or will take, to eliminate or mitigate the effect of the bias.

- B. Retrospective Review – The University is required to document retrospective reviews. Such documentation shall include, but not necessarily be limited to, all of the following key elements, as applicable:
1. Sponsoring agency(ies);
 2. Award/Contract number;
 3. Project number;
 4. Project title;
 5. PD/PI or contact PD/PI if a multiple PD/PI model is used;
 6. Name of the Investigator with the FCOI;
 7. Name of the entity with which the PI has a financial conflict of interest;
 8. Reason(s) for retrospective review;
 9. Detailed methodology used for the retrospective review (e.g., methodology of the review process, composition of the review panel, documents reviewed);
 10. Findings of the review; and
 11. Conclusions of the review.
- C. Based on the results of the retrospective review, if appropriate, the Designated Division Vice President shall update the previously submitted FCOI report, specifying what actions will be taken to manage the conflict of interest going forward. If bias is found, the Designated Division Vice President 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(es) 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 Designated Division Vice President will submit FCOI reports annually. Depending on the nature of the financial conflict of interest, the COIC may determine that additional interim measures are necessary regarding the University Personnel's participation in the funded research project/academic activity between the date that the financial conflict of interest or the individual's noncompliance is determined and the completion of the Institution's retrospective review.

XII. Management of Conflicts (Interest/Commitment/Financial)

- A. When the COIC reasonably determines that such conflict could directly and significantly affect the design, conduct, or reporting of sponsored research/academic activities, the COIC may recommend that a proposal shall not continue or 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. Disclosing significant financial interests (e.g., when presenting or publishing the research);
2. Disclosing financial conflicts of interest directly to participants for research projects involving human subjects;
3. Monitoring research by independent reviewers;
4. Modifying research plan;
5. Changing 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; and
6. Divesting significant financial interest(s) (e.g., sale of an equity interest); or
7. Severing relationships that create conflicts.

B. If the COIC determines that the interest of scientific progress, technology transfer, or the public health and welfare outweigh the potential negative impact that may arise from a significant financial interest, and imposing conditions or restrictions would either be ineffective or inequitable, then the COIC may allow the research/academic activity to go forward without imposing such conditions or restrictions, if not prohibited by funding source.

XIII. When the University Untimely Identifies a Financial Conflict of Interest

- A. Whenever the University identifies a significant financial interest that was not disclosed timely by an Investigator or, for whatever reason, was not previously reviewed by the University during an ongoing funded research project, the designated official(s) shall, within sixty (60) days:
1. Review the significant financial interest;
 2. Determine whether it is related to funded research;
 3. Determine whether a financial conflict of interest exists; and, if so
 4. Implement a management plan that shall specify the actions that have occurred and will be taken to manage such financial conflict of interest going forward.

XIV. Sanction

Pursuant to Section 1012.977(3), Florida Statutes, an employee who has failed to disclose any outside activity or financial interest as required by this Policy shall be suspended without pay pending the outcome of an investigation which shall not exceed 60 days. Upon conclusion of the investigation, the University or entity may terminate the contract of the employee, current awards and/or contracts, and may determine an investigator ineligible to receive future awards and/or contracts. The University may take additional administrative or disciplinary action under applicable University regulations, policies, and collective bargaining agreements.

XV. University Personnel Training

- A. University Personnel must complete training prior to engaging in research at least every four (4) years, and within 30 days if one or more of the following circumstances occur:

1. University Conflict of Interest policies change in a manner that affects University Personnel requirements;
2. University Personnel is new to the University; and
3. The University finds that the University Personnel is noncompliant with the University's policy or management plan.

XVI. Record Retention and External Reporting

Records of conflict disclosures and actions taken to manage conflicts of interest shall be retained at least three years beyond the termination or completion of the project/academic activity to which they relate, or the resolution of any government action involving those records, whichever is longer. The Designated University Division is responsible for filing a report with the requisite Federal agency a report outlining the University's inability to satisfactorily manage a conflict of interest.

Attachment(s)	
Hyperlink Addresses	<u>42 CFR Part 50 Subpart F</u> <u>45 CFR Part 94</u> <u>DOE O 486.1</u> <u>DOE O 142.3B</u> <u>Uniform Guidance 2 CFR §200.112 Conflict of Interest and 2 CFR §200.113</u> <u>Section 1004.28, F.S. 1012.977</u> <u>University Regulations 1.019</u> <u>University Regulations 1.020</u> <u>University Regulations 10.121</u> <u>University Regulations 10.122</u> <u>286.101, F.S.</u>