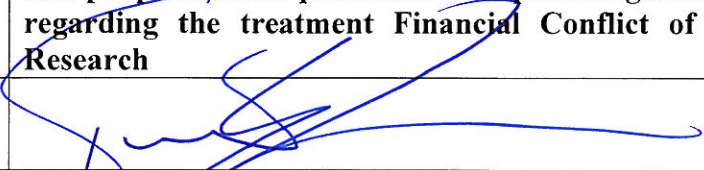




Florida Agricultural & Mechanical University
Division of Research

INTERNAL OPERATING MEMORANDUM

Memorandum No. 16A.021

Subject:	Financial Conflict of Interest Governing Research	
Authority:	Division of Research	Date: 08/13/2012 Revised: 01/12/2016
Related References	45 CFR Part 94 (contracts)	
Purpose	The purpose of this procedure is to provide guidance to the University regarding the treatment Financial Conflict of Interest Governing Research	
Signature of Approving Authority		

1.0 GENERAL INFORMATION

Per 45 CFR Part 94 (contracts): This regulation promotes objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct, and reporting of research funded under federal grants or cooperative agreements will be free from bias resulting from Investigator financial conflicts of interest.

2.0 DEFINITIONS

- 2.1 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.
- 2.2 Financial Interest** - means anything of monetary value, whether or not the value is readily ascertainable.
- 2.3 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).
- 2.4 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).
- 2.5 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.
- 2.6 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.

- 2.7 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.

3.0 RESPONSIBILITIES

- 3.1 Principal Investigator** is responsible for the design, conduct, or reporting of their sponsored program(s) at the time of proposal submission and ensure that each Investigator files an FCOI Annual Disclosure Form as required. If an "Investigator's" significant financial interest requires a management plan, the Principal Investigator will collaborate with the Conflict of Interest Committee (COIC) to develop the plan. PI must submit an FCOI Annual Disclosure Form, and if needed, an FCOI Disclosure Attachment, by May 1 of each year. A new form must be submit within 30 days if there is a material change (an acquisition of a significant financial interest) to the information provided, should a management plan be required.
- 3.2 Deans, Institute Director, and Department Heads** are responsible for compliance with and implementation of this procedure within their schools or departments. The head of the responsible unit (or designee) is responsible for collaborating with the Principal Investigator, as applicable in the development, completion, and oversight of management plans within their school, and/or department.
- 3.3 Subgrantees, Contractors, and Collaborators** - who are working under subagreements with Florida A&M University that are funded by the Public Health Service (PHS), must comply with the PHS regulations (42 CFR Part 50 Subpart F, grants and 45 CFR Part 94, contracts) by following this FAMU procedure or by providing appropriate assurances to FAMU. These individuals must report identified financial conflicts of interest to interest to the Division of Research, Office of Sponsored Programs.

4.0 PROCEDURES

- 4.1** Principal investigator must complete the required FCOI training and FCOI Disclosure form prior to the submission of grant through the Office of Sponsored Programs in the Division of Research.
- 4.2** The Office of Sponsored Programs (OSP) reviews the documentation prior to submission of the grant via eRA Commons. If a Significant Financial Conflict of Interest is disclosed on the FCOI Form, the FCOI Disclosure attachment must be completed and submitted the OSP.
- 4.3** The OSP will submit the Disclosure Form to the Division Office of Audit and Compliance.
- 4.4** If the Office of Audit and Compliance determines that such interest may affect the design, conduct, or reporting of the project the disclosure will be sent to the Office of Animal Welfare and Research Integrity who will convene the Conflict of Interest Committee (COIC) for review and design of management plan.
- 4.5** The COIC will meet with the Deans, Department Heads and Principal Investigator to discuss the terms of the conflict and then design a management plan. COIC will offer recommendations for compliance to the Principal Investigator within sixty (60) days of receipt of the financial conflict of interest.
- 4.6** The Division of Research will file with the requisite Federal agency an inability of the University to satisfactorily manage a conflict of interest.

- 4.7 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.
- 4.8 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.
- 4.9 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.

5.0 RECORDS

The Office of Sponsored Programs will maintain records in accordance with applicable regulations. The appropriate record retention guideline should be followed for retention and disposition of documents