

	Florida Gulf Coast University Policy Manual	Policy: 2.018
	Financial Conflict of Interest in Sponsored Research	Responsible Office: Office of Research and Graduate Studies

A. POLICY STATEMENT

In accordance with the federal requirements applicable to grants from the National Science Foundation (NSF), the National Institutes of Health (NIH), and other federal agencies, the University has established procedures for the disclosure of financial conflicts of interest and the appropriate management of actual or potential conflicts of interest. The objective of this Policy and the federal regulations on which it is based is to promote objectivity in research by establishing standards to ensure there is no reasonable expectation that the design, conduct, or reporting of research funding under federal grants will be biased by any conflicting financial interest of an investigator.

All faculty, staff or students responsible for the design, conduct, or reporting of research under the terms of a federal grant or contract are required to disclose to the Associate Vice President for Research all significant financial interests, as defined in this Policy, of the investigator or the investigator's spouse, partner, and dependent children.

B. REASON FOR POLICY

The federal government requires that the University establish and administer a financial disclosure policy for those investigators applying for federal funds and create a program for training investigators in that policy. This Policy is designed to ensure appropriate management of actual or potential conflicts of interest. This Policy is designed to fulfill the requirements of grantee institutions as put forth in the NIH guidelines applicable to all Public Health Service (PHS) affiliated agencies. This Policy is also designed to comply with the NSF conflict of interest policies.

C. APPLICABILITY AND/OR ACCOUNTABILITY

This Policy is applicable to all faculty, staff, and students who apply for, receive, plan to participate in, or are participating in sponsored research under a federal grant.

D. DEFINITION OF TERMS

1. *Financial Conflict of Interest (FCOI)*: Exists when a significant financial interest, defined below, could directly and significantly affect the design, conduct, or reporting of federally-funded research or educational activities.
2. *Investigator*: The project director or principal investigator and any other person,

regardless of title or position, who is responsible for the design, conduct, or reporting of research funded by a federal agency, or proposed for such funding, which may include, for example, collaborators or consultants.

3. *Research*: Systematic investigation, study or experiment designed to develop or contribute to generalizable knowledge relating broadly to public health, including behavioral and social sciences, and for which research funding is available from a PHS awarding component (e.g., NIH) through a grant or cooperative agreement, including research grants, career development awards, center grants, individual fellowship awards, infrastructure awards, institutional training grants, program projects, or research resources awards.
4. *Significant Financial Interest* (SFI) means either a. or b. below:
 - a. A financial interest consisting of one or more of the following interests of the Investigator (and those of the Investigator's spouse, partner, and dependent children) that reasonably appears to be related to the Investigator's institutional responsibilities:
 - 1) With regard to any publicly traded entity, a SFI exists if the value of any remuneration received from the entity in the twelve months preceding the completion of this questionnaire and the value of any equity interest in the entity as of the date of completion of this questionnaire, when aggregated, exceeds \$5,000 (or \$10,000 in the case of NSF funding). 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 stock, stock option, or other ownership interest, as determined through reference to public prices or other reasonable measures of fair market value;
 - 2) With regard to any non-publicly traded entity, an SFI exists if the value of any remuneration received from the entity in the twelve months preceding the completion of this questionnaire, when aggregated, exceeds \$5,000 (in the case of NSF funding, \$10,000), or when the Investigator (or the Investigator's spouse, partner, or dependent children) owns any equity interest, regardless of dollar value (or in the case of NSF funding, more than 5% ownership interest in any single entity); and/or
 - 3) Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.
 - b. In the case of funding by PHS affiliated agencies, 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, but excluding travel that is reimbursed or sponsored by (i) a federal, state, or local government agency, (ii) an institution of higher

education, or (iii) an academic teaching hospital, medical center, or research institute that is affiliated with an institution of higher education. The Investigator must disclose the purpose of the trip, the identity of the sponsor and/or organizer, the destination and its duration. Additional information, including the estimated cost of travel, may be requested by the institutional official and must be furnished upon request.

c. SFI does not include the following types of financial interests:

- 1) Salary, royalties, or other remuneration paid by FGCU to the Investigator if the Investigator is currently employed or otherwise appointed by the University, including intellectual property rights assigned to the University and agreements to share in royalties related to such rights;
 - 2) Income from investment vehicles, such as mutual funds and retirement accounts, as long as the Investigator does not directly control the investment decisions made in these vehicles;
 - 3) Income from seminars, lectures, or teaching engagements sponsored by a federal, state, or local government agency, an institution of higher education, an academic teaching hospital, a medical center, or a Research institute that is affiliated with an institution of higher education; or
 - 4) Income from service on advisory committees or review panels for a federal, state, or local government agency, an institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education.
5. *University Reviewer*: The Associate Vice President for Research, or designee(s), which may be a committee designated by the Associate Vice President for Research.

E. PROCEDURES

1. Required Disclosure

- a. Investigators must provide all required financial disclosures by completing the Financial Disclosure Form located on the Office of Research and Graduate Studies (“ORGS”) website at the time a proposal is submitted.
- b. In addition, Investigators must update the Financial Disclosure Form:
 - 1) Within thirty (30) days of discovering or acquiring (e.g., through purpose, marriage or inheritance) any new SFI; and
 - 2) Annually within the period of the award, beginning with the anniversary date of

the original disclosure.

c. Travel

Investigators must also disclose reimbursed or sponsored travel related to their institutional responsibilities.

2. Review of Financial Disclosures

The following process shall apply to financial disclosures submitted by Investigators:

a. Determination of Financial Conflicts of Interest

The University Reviewer shall review each disclosed SFI and determine whether such SFI relates to federally-funded Research. If so related, the University Reviewer shall determine whether an FCOI exists, and if so, determine what condition or restrictions, if any, will be imposed to manage, reduce, or eliminate such conflict of interest. The University Reviewer may, depending on the scope of the potential conflict, request that additional staff or faculty serve on an ad hoc review committee to assist in its timely review.

b. Management of Financial Conflicts of Interest

If the University Reviewer determines that an SFI constitutes an FCOI, the University Reviewer will convene a committee consisting of faculty, senior staff, and/or outside experts (the "COI Committee") whose make-up shall be determined in the discretion of the University Reviewer. The COI Committee will review the Research, the SFI in question, and the areas of conflict, and devise a plan for the management of the FCOI. The management plan may include conditions or restrictions to manage, reduce, or eliminate the FCOI, which may include, but are not limited to:

- 1) Monitoring of Research by independent reviewers;
- 2) Modification of the Research plan;
- 3) Disqualification from participation in the portion of the federally-funded Research that would be affected by SFI;
- 4) Reduction or elimination of SFI;
- 5) Severance of relationships that create conflicts; or
- 6) Public disclosure of the FCOI.

c. The Investigator will be consulted as to the implementation of the Management Plan;

the Investigator must agree to the plan before the Research can proceed. If the COI Committee and the Investigator cannot agree upon a management plan, the relevant regulatory bodies and funding agencies will be notified.

3. Reporting of Financial Conflicts of Interest

a. Sponsoring Agency

SFI that are determined by the University Reviewer to be an FCOI will be reported to the sponsoring agency in accordance with its requirements within sixty (60) days of the original disclosure.

b. Public Request

As required by sponsoring agency regulations, information on the nature of such Conflicts of Interest will be made available to members of the public by the University Reviewer in response to inquiries specifying the Investigator name and the Research project in question within five (5) business days of receipt of such requests.

4. Investigator Non-Compliance

a. In the event of an Investigator's failure to comply with this Policy, the University Reviewer in conjunction with the Investigator's supervisor may suspend all relevant activities.

b. Refer the matter to the appropriate Vice President for disciplinary action in accordance with University regulations or the Collective Bargaining Agreement, as applicable.

c. In addition, if the University Reviewer determines that an FCOI was not identified or managed in a timely manner, including but not limited to an Investigator's failure to disclose a SFI that is determined to be an FCOI, or failure by an Investigator to materially comply with a management plan for an FCOI, a committee appointed by the University Reviewer will complete a retrospective review of the Investigator's activities and the Research project to determine whether the Research conducted during the period of non-compliance was biased in the design, conduct or reporting of the Research. Documentation of the retrospective review shall include:

- 1) The project number,
- 2) The project title,
- 3) Principal Investigator,
- 4) Investigator with the FCOI,

- 5) Name of entity with which the Investigator has the FCOI,
 - 6) Reason(s) for the retrospective review,
 - 7) Detailed methodology used for the retrospective review, and
 - 8) Findings and conclusion of the review.
- d. If the retrospective review involves a PHS agency, the University Reviewer will update any previously submitted report to the PHS or the prime PHS-awardee relating to the Research, specifying the actions that will be taken to manage the FCOI going forward. If bias is found, the report will include a mitigation report in accordance with the PHS regulations, including a description of the impact of the bias on the Research project and the plan of action to eliminate or mitigate the effect of the bias.

5. Records

The University shall maintain records of all financial disclosures and of all actions taken to resolve the FCOI for at least three (3) years beyond the termination or completion of the grant to which they relate, or until the resolution of any federal action involving those records; or in accordance with the University record retention schedule, whichever is longer.

6. Training

a. Investigators on NIH/PHS Proposals

Each Investigator on projects funded by or proposed to NIH or other PHS affiliated agencies must complete training on Conflict of Interest. Investigators must complete such training prior to participation in PHS-funded Research and every four years thereafter as long as the project is active. This educational requirement is met by completing the "Conflicts of Interest" course located on the CITI website. Instructions for registering and taking this course are found on the ORGS webpage.

b. Investigators on Non-NIH/PHS Proposals

For Investigators sponsored by or seeking funding from NSF and/or other federal agencies, as well as any Investigators initiating Research sponsored by a private, for-profit entity, the above training activities are optional but recommended.

7. Subrecipients

The University is responsible for ensuring all subrecipients' compliance with the applicable federal regulations regarding an FCOI. To this end, the University shall enter a

written agreement with each subrecipient that shall specify whether this Policy, or the applicable policy of the subrecipient's institution, will apply to subrecipient Investigators. Said agreement will specify the timing for reporting of an FCOI by subrecipients to the University to enable the timely review and reporting of such FCIO in compliance with funding agency requirements.

Related Information

National Science Foundation Proposal & Award Policies and Procedures Guide, Chapter IX, Grantee Standards

Financial Interest Disclosure Procedures for the National Science Foundation

Office of Management and Budget's Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards

Florida Code of Ethics for Public Officers and Employees, Section 112.311 et. seq., Florida Statutes

Regulation FGCU-PR5.012 Outside Employment/Activities

Regulation FGCU-PR6.019 Standard of Conduct (Procurement)

Specific Authority

42 CFR Part 50 Subpart F, Promoting Objectivity in Research

45 CFR Part 94

History of Policy

New 03/12/2019

APPROVED

*s/Michael V. Martin
Michael V. Martin, President

March 12, 2019
Date