

FLORIDA STATE UNIVERSITY

POLICY 7A-21

FINANCIAL CONFLICT OF INTEREST DISCLOSURE

Responsible Executive: Gary K. Ostrander, Vice President for Research

Approving Official: Gary K. Ostrander, Vice President for Research

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I. Introduction

Florida State University is committed to ensuring that research and scholarly activities are carried out under the highest standards of ethical conduct and adhere to applicable governmental regulations and University policies governing the conduct of research. The University's overall

policy on conflict of interest is that none of its faculty or staff shall engage in any activities that place them in a conflict of interest between their official activities and any other interest or obligation. Faculty and staff relationships with outside entities must support the FSU mission and its principal objectives of teaching, research, and service, but should not create inappropriate external biases affecting the freedom of faculty to pursue all areas of academic inquiry.

Certain funding agencies have implemented regulations promoting objectivity in research by requiring that a university applying for extramural research funding insure that there is no reasonable expectation that the design, conduct, and reporting of the research to be funded pursuant to the application will be biased by any significant financial interest of any Investigator working on the research. The University has created this policy on significant financial interest disclosure to prevent or resolve, through management and/or mitigation, real or apparent conflicts that may exist in relation to research, instruction, and service activities undertaken by University investigators.

This policy supplements the existing university policy contained in the FSU Faculty Handbook and other university policies and procedures on this subject.

II. Policy

A. Definitions

Definitions related to significant financial interest disclosure regulations vary among funding agencies. Investigators should consult the applicable funding agency regulations and FSU's disclosure procedures for definitions of terms such as *significant financial interests (SFIs)*, *financial conflict of interest (FCOI)*, and *investigator*.

B. Institutional Responsibilities

FSU shall maintain an up-to-date, written, and enforced policy on financial conflicts of interest and maintain a publicly available web site containing the Policy, the Investigator's responsibilities regarding disclosure of significant financial interests (SFIs), applicable Federal regulations, and associated procedures.

FSU shall provide required certifications in each application for funding. Such certification may include the following: (1) the Institution has an up-to-date, written, and enforced administrative process to identify and manage financial conflicts of interest with respect to all research projects for which funding is sought or received from the agency; (2) FSU shall promote and enforce Investigator compliance with funding agency requirements including those pertaining to disclosure of significant financial interests; (3) FSU shall manage FCOI and provide initial and ongoing FCOI reports to the funding agency consistent with the regulations; and (4) FSU agrees to make information available, promptly upon request, to the funding agency relating to any Investigator disclosure of financial interests and the Institution's review of, and response to, such disclosure, and shall fully comply with the regulation subpart governing financial conflict of interest.

C. Investigator Responsibilities

Investigators are required to disclose their SFIs, as well as the SFI's of the Investigator's spouse and dependent children, in accordance with the regulations governing their individual proposal and/or award. In addition, as required by the funding agency, such Investigator shall also submit an updated disclosure of SFIs at least annually in accordance with the specific time period prescribed by the Institution, during the period of the award. Such disclosure shall include any information that was not disclosed initially to the Institution or in a subsequent disclosure of SFIs (e.g., any FCOI identified on an award that was transferred from another Institution), and shall include updated information regarding any previously disclosed SFI (e.g., the updated value of a previously disclosed equity interest). The updated disclosure of SFIs shall be submitted within thirty days of discovering or acquiring (e.g. through purchase, marriage, or inheritance) a new significant financial interest.

Certain agencies require that Investigators undergo periodic training on financial conflicts of interest regulations and Investigator responsibilities regarding disclosure of significant financial interests. Training requirements for these agencies are described in the applicable procedures (Paragraph E), as well as published on the Research Compliance Programs website at <http://www.research.fsu.edu/researchcompliance/>. FSU urges all investigators to take advantage of this training.

D. Subrecipient/Subcontractor Disclosures

If FSU carries out the research through a subrecipient (e.g. subcontractors or consortium members) and FSU is the awardee institution, then FSU shall incorporate as part of a written agreement with the subrecipient specific terms that establish whether the financial conflicts of interest policy of FSU or that of the subrecipient shall apply to the subrecipient's Investigators.

If the subrecipient's policy applies, the subrecipient must certify as part of the agreement that its policy complies with the federal regulations regarding financial conflict of interest. If the subrecipient has so certified, then additionally, the agreement must specify the time period for the subrecipient to report all identified FCOI to the awardee FSU. Such time period shall be sufficient to enable FSU to provide timely FCOI reports to the funding agency as required by federal disclosure regulations.

If the subrecipient cannot certify as described above, then the agreement shall state that the subrecipient investigators are subject to FSU's financial conflicts of interest policy for disclosing SFIs that are directly related to the subrecipient's work for FSU. The agreement shall specify the time period for the subrecipient to submit all Investigator disclosures of SFIs to FSU's IO. The time period shall be sufficient to enable the awardee FSU to comply timely with its review, management, and reporting obligations pursuant to federal regulation.

E. Disclosure Procedures

Investigators are required to disclose their SFIs, as well as the SFI's of the Investigator's spouse and dependent children, in accordance with the regulations governing their individual proposal and/or award. Because funding agencies have unique disclosure requirements that may change from time to time, the Office of Research Compliance Programs will publish disclosure procedures, reflecting the requirements for each of these agencies, on its website at <http://www.research.fsu.edu/researchcompliance/>. Please refer to these procedures and agency regulations as required.

F. Disclosure Review Process

The Vice President for Research shall designate an Institutional Official ("IO"), to solicit and review disclosures of SFIs from each Investigator who is planning to participate in, or is participating in, research funded by an agency which requires such disclosure.

The IO will determine if an Investigator's SFI is an FCOI. An FCOI exists when the Institution, through its designated official, reasonably determines that the SFI could directly and significantly affect the design, conduct, or reporting of the research. In determining if an Investigator's SFI is related to the research, and if so, whether the SFI is a FCOI, the IO may consider the role of the Investigator and the opportunity (if any) to bias the results, the nature of the research being proposed, and the value of the SFI in relation to the size and value of the entity. In addition, the IO may also consider the following factors:

1. Whether the research is of a basic or fundamental nature directed at understanding basic scientific processes;
2. Whether the degree of replication and verification of research results is such that immediate commercialization or clinical application is not likely;
3. Whether the goal of the research is to evaluate an invention linked to the SFI (such as where the SFI is a patent, or an interest in a company that has licensed the invention);
4. Where the research involves human subjects, whether there are double blind conditions or the involvement of a data and safety monitoring board;
5. Where the SFI is in a privately held company, whether the researcher's SFI could result in the researcher having influence over company decisions, or whether the research could have a significant impact on the company's business or financial outlook;
6. The magnitude of the SFI's (e.g., the amount of consulting, or the percentage or value of equity);
7. The number and nature of relationships an Investigator has with an entity. Multiple entanglements can create a relationship with an outside entity that is stronger than the sum of the parts;
8. Whether the goal of the research is to validate or invalidate a particular approach or methodology that could affect the value of the SFI;
9. Whether other scientific groups are independently pursuing similar questions; or

10. Whether sufficient external review of the research conducted and the reporting of research results exist to mitigate undue bias;
11. Whether the goal of the project is a comparative evaluation of a technology in which an investigator has a SFI; or
12. Whether the project involves a subaward to an entity in which the Investigator has a SFI.

Prior to initiating work and expending any funds related a research project subject to disclosure requirements, the IO shall review all Investigator disclosures of SFIs; determine whether any SFIs relate to the funded research; determine whether a financial conflict of interest exists; and if so develop and implement a management plan that shall specify the actions that have been or shall be, taken to manage such financial conflict of interest. The IO may consult with the investigator, the investigator's supervisor, chair, dean, or Vice President for Research at any time during this process.

G. Management Plan

FSU shall take appropriate action to manage financial conflicts of interest, including any FCOIs of a subrecipient. Management of an identified financial conflict of interest requires development and implementation of a management plan, and if necessary, a retrospective review and mitigation report as required by federal regulation.

The key elements of the management plan shall include:

- Role and principal duties of the conflicted Investigator in the research project;
- Conditions of the management plan;
- How the management plan is designed to safeguard objectivity in the research project;
- Confirmation of the Investigator's agreement to the management plan;
- How the management plan will be monitored to ensure Investigator compliance; and
- Other information as needed.

Examples of conditions or restrictions that might be imposed to manage a financial conflict of interest include, but are not limited to:

- Public disclosure of financial conflicts of interest (e.g. when presenting or publishing the research);
- For research involving human subjects disclosure of financial conflicts of interest directly to participants;
- Appointment of an independent monitor capable of taking measures to protect the design, conduct, and reporting of the research against bias resulting from the financial conflict of interest;
- Modification of the research plan;
- Change of personnel or personnel responsibilities, or disqualification of personnel;
- Reduction or elimination of the financial interest (e.g. sale of an equity interest); or
- Severance of relationships that create financial conflicts.

H. Non-Compliance

Whenever FSU identifies an SFI that was not disclosed timely by the Investigator or, for whatever reason, was not previously reviewed by the Institution during an on-going research project subject to disclosure regulations (e.g. was not timely reviewed or reported by a subrecipient), the IO shall, within 60 days:

- Review the significant financial interest;
- Determine whether it is related to the research;
- Determine whether a financial COI exists; and if so:
- Implement a management plan that shall specify the actions that have been, and will be, taken to manage the COI going forward.

In addition, whenever an FCOI is not identified or managed in a timely manner including: (1) failure by the Investigator to disclose a SFI that is determined by FSU to constitute an FCOI, (2) failure by FSU to review or manage such a financial COI, or (3) failure by the Investigator to comply with an FCOI management plan, FSU shall, within 120 days of FSU's determination of noncompliance, complete a retrospective review of the Investigator's activities and the research project to determine whether any research, or a portion thereof, conducted during the time period of the noncompliance, was biased in the design, conduct, or reporting of such research.

FSU shall document the retrospective review; and such documentation shall include, but not be limited to, the following key elements: (1) project number; (2) project title; (3) PD/PI; (4) name of the Investigator with the FCOI; (5) name of the entity with which the Investigator has an FCOI; (6) reason 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 review); (8) findings of the review; and (9) conclusions of the review.

Based on the results of the retrospective review, if appropriate, FSU shall update any previously submitted FCOI report, specifying the actions that will be taken to manage the financial conflict of interest going forward. If bias is found, then FSU shall, if required, notify and submit a mitigation report to the funding agency.

The mitigation report must include the key elements documented in the retrospective review above and a description of the impact of the bias on the research project and FSU'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, FSU will submit FCOI reports annually as required by Federal regulations. Depending on the nature of the FCOI, FSU may determine that additional interim measures are needed with regard to the Investigator's participation in the research between the date that the FCOI or the Investigator's noncompliance is determined and the completion of FSU's retrospective review.

Whenever FSU implements a management plan, it shall periodically monitor Investigator compliance with the management plan until the completion of the project.

I. Disciplinary Action

Any failure by an Investigator to adhere with this Policy may be cause for disciplinary action pursuant to the FSU Faculty Handbook, Collective Bargaining Agreement, and other applicable employee disciplinary policies. Additionally, in the event of an Investigator's failure to comply with this Policy, FSU may suspend all relevant activities or take other disciplinary action until the matter is resolved or other action deemed appropriate by the IO (in consultation with the chair, dean, and Vice President for Research) is implemented.

An IO's decision to impose sanctions on an Investigator because of failure to comply with this Policy, or failure to comply with the decision of the IO, will be described in a written explanation of the decision to the Investigator, and the individual will have the right to appeal the decision. An appeal may be made by the affected party, in writing, to the Vice President for Research, within 10 days of receipt of notice of the decision. The review and decision of the Vice President for Research shall be final.

J. Reporting to Funding Agencies

FSU shall provide all reports and notifications to funding agencies as required by the applicable disclosure regulations.

K. Record Retention

The IO will retain all disclosure forms, conflict management plans, reports, and other pertinent documents for a period of three years from the date the final expenditure report is submitted to the funding agency, or as required by Federal regulations.

L. Public Accessibility

If required by Federal disclosure regulations, prior to the expenditure of any funds an award subject to these disclosure requirements, FSU shall ensure public accessibility, and provide a written response to any requestor within five business days of receipt of a request, of information concerning any significant financial interest disclosed to FSU that meets the following criteria:

- FSU determines that the SFI was disclosed and is still held by the Investigator as defined herein;
- FSU determines that the SFI is related to the research; and
- FSU determines that the SFI is a FCOI.

The information that FSU makes available by written response to any requestor shall include information as required by Federal regulations. Written requests for information concerning significant financial interests shall be directed to FSU's Institutional Official:

Director of Research Compliance Programs, Office of Research, 2021 Westcott North,
Tallahassee, FL 32306-1330.

If FSU responds to written requests to ensure public accessibility, then FSU will note in its written response that the information provided is current as of the date of the correspondence and is subject to updates, on at least an annual basis and within sixty days of FSU's identification of a new FCOI, which should be requested subsequently by the requestor.

M. Confidentiality

To the extent permitted by law, all disclosure forms, conflict management plans, and related information will be confidential. However, FSU may make such information available to an agency funding research of the faculty member, to a requestor of information concerning financial conflict of interest related to Federal funding or to the primary entity who made the funding available to FSU, if requested or required. If FSU is requested to provide disclosure forms, conflict management plans, and related information to an outside entity, the Investigator will be notified.

III. Legal Support, Justification, and Review of this Policy

PHS Conflict of Interest Regulations, *42 CFR Part 50, Subpart F*

NSF Conflict of Interest Regulations, *NSF Proposal and Award Policy and Procedures Guide*, Chapter IV.A.

FSU Faculty Handbook Section 4

State of Florida Statutes, Chapter 112 Part III and 1004.22

These policies will be reviewed periodically and make changes when necessary.

Gary K. Ostrander, Vice President for Research
February 18, 2015