

**UF Research Policy:
Disclosure of Financial Interests and
Management of Conflicts of Interest Related to Research**

I. References.

42 CFR 50, Subpart F “Promoting Objectivity in Research” (“PHS Regulation”)

UF Regulation 1.011 Disclosure and Regulation of Outside Activities and Financial Interests (“UF Regulation on Conflicts”)

UF Policy on Conflicts of Commitment and Conflicts of Interest (“UF Policy on Conflicts”)

II. Policy Summary.

- A. Scope.** This policy and related UF Research guidelines set forth the process to identify and manage conflicts of interest related to research. The UF Policy on Conflicts is UF’s comprehensive policy on conflicts of interest, which requires UF employees to provide appropriate disclosure of outside activities and financial interests. The Vice President for Research (VPR) will designate a Research Conflict of Interest Administrator (RCOI Administrator) who will serve as the institutional official responsible for this policy and the oversight, review and management of conflicts in research. The VPR may also convene a committee to assist with the implementation of this policy and any related procedures.
- B. Applicability.** This policy applies to UF employees when they are Investigators. Additionally, UF shall comply with all applicable statutory and regulatory requirements published by federal agency sponsors regarding Financial Conflict of Interest (FCOI) related activities sponsored by those agencies, such as the Public Health Service (PHS) Regulation.
- C. Definitions.** Unless otherwise defined herein, terms used in this policy shall have the meanings given to them in the [UF Policy on Conflicts](#) and the [PHS Regulation](#).

III. Disclosures; Review of Disclosures; and Management.

- A. Disclosure Requirement.** When required by certain sponsors, Investigators must disclose any Significant Financial Interests (SFI) for themselves and their immediate family members that reasonably appear to be related to that Investigator’s Institutional Responsibilities at the time of proposal submission. At award, all Investigators must disclose any SFI for themselves and their immediate family members. Investigators in human subject research must disclose financial and personal interests to the reviewing Institutional Review Board (IRB) at the time of protocol submission. Investigators must disclose new SFI within 30 days of discovery or acquisition and at least annually required by the UF Regulation on Conflicts.

B. University Review.

- 1) Review. The RCOI Administrator will conduct reviews to assess whether an Investigator's disclosed SFI involves related research, and if so, whether or not the SFI could directly and significantly affect the design, conduct, or reporting of research, thus presenting an FCOI, or an appearance thereof. Relatedness determinations consider whether the SFI could be affected by the research or is in an entity whose financial interest could be affected by the research. FCOI determinations take into account:
 - a. The nature and extent of an Investigator's role on a project;
 - b. The nature and extent of an Investigator's SFI, and;
 - c. The nature of the research activity under review.
- 2) Timing of Reviews. Reviews and determinations should occur prior to expenditure of funds for new awards and within 60 days of a newly-disclosed or discovered SFI. Reviews and determinations should occur prior to the addition of new Investigators during the life of an award.
- 3) Relatedness Review. The RCOI Administrator may determine there is not related research. The RCOI Administrator may refer reviews to an appropriate subject matter expert or a COI committee for further evaluation and disposition. If the RCOI Administrator determines there is related research, the RCOI Administrator will initiate an FCOI Review.
- 4) FCOI Review. The RCOI Administrator determines whether the SFI represents an FCOI. If a SFI is determined to be an FCOI, the RCOI Administrator will proceed to manage the conflict, as outlined in section C. Management, below.

C. Management. If an FCOI is determined to exist, the RCOI Administrator, will develop a management plan to manage, reduce, or eliminate the FCOI.

- 1) Management Plans. Depending on the nature of the FCOI and nature of the research activity, management plan controls may include:
 - a. Disclosure of the FCOI (to study teams, collaborators, the IRB, human research participants, and in presentations and publications);
 - b. Reduced role in the research, and/or independent review of research data and results;
 - c. Additional conflict of interest management strategies, as appropriate,

d. In extreme cases, prohibition from participating in research or divestment of financial interests may be required.

2) Agreement to the Management Plan. Investigators must agree to management plans in order to engage in research where an FCOI exists.

D. Reporting. Pursuant to law or sponsor requirements, the RCOI Administrator will provide to the sponsor initial and ongoing reports describing an FCOI and related management.

1) For PHS-funded research, FCOI reports must be submitted to the PHS awarding component prior to the expenditure of funds for new projects, within 60 days of newly determined FCOI (whether the result of a new Investigator, newly disclosed SFI, or identification of an SFI that was not disclosed timely or an SFI that was not previously reviewed), and on an annual basis during the life of the project.

2) In addition, PHS requires UF to make available to the public, upon request, specific information regarding FCOI relative to senior/key personnel and PHS-funded research. UF is required to provide specific information relative to such public requests within five business days of the request.

E. FCOI Management Review. The conditions of, and compliance with, Investigator management plans are reviewed on at least an annual basis by the RCOI Administrator. On an ad hoc basis, the RCOI Administrator may also conduct independent monitoring and verification to ensure that the conditions of the management plans are being met.

F. Subrecipients. UF must apply relevant originating sponsor conflict of interest requirements to subrecipients. Therefore, if required by the originating sponsor, UF must identify whether or not a subrecipient has a conflict of interest policy compliant with applicable originating sponsor conflict of interest requirements. If a subrecipient does not have a conflict of interest policy compliant with applicable originating sponsor conflict of interest requirements, in order to proceed with the UF collaboration, the subrecipient must agree to abide by this policy relative to the Subrecipient Investigators and the specific subrecipient research activity for the duration of that activity. The subaward must incorporate terms that establish whether this policy or that of the subrecipient will apply to subrecipient investigators, and obligations of the subrecipient relative to conflict of interest in either case.

G. Training. Investigators may be required to complete research conflict of interest training.

1) For PHS Investigators, UF will require the completion of training before engaging in PHS funded research, at least every four years thereafter, and immediately when:

- a. UF revises its financial conflict of interest policies or procedures in any manner that affects the requirements of PHS Investigators; or
- b. A PHS Investigator is new to UF; or
- c. UF finds that a PHS Investigator is not in compliance with this policy or applicable management plan.

H. Record Retention. UF will maintain all review files and associated reports and management plans for three (3) years after any applicable research project's final financial report is submitted to a sponsor, or until three (3) years after the final action has been taken on any audit, litigation, or claim.

IV. Non-Compliance and Enforcement.

A. Examples of Non-Compliance: The following are examples of noncompliance with this policy:

- 1) Failure to submit a timely disclosure (e.g. more than 30 days after discovery or acquisition of a new SFI);
- 2) Submission of an incomplete, erroneous or misleading initial, updated or annual disclosure;
- 3) Failure to disclose information as required by this policy;
- 4) Failure to comply with prescribed management plans; or
- 5) Other instances as determined by the RCOI Administrator.

B. Non-Compliance. Any instance of Investigator noncompliance may require that the Investigator repeat UF's research conflict of interest training. Additional disciplinary action for noncompliance with this policy will be decided in accordance with applicable UF disciplinary policies and procedures.

C. Non-Compliance Involving PHS-funded Research. Whenever an FCOI is not identified or managed in a timely manner, including failure by the Investigator to disclose an SFI, or failure of an Investigator to comply with the conditions of a management plan, UF must conduct a retrospective review of the Investigator's research activities on the project to determine if there is bias in the design, conduct, or reporting of the research resulting from the FCOI.

- 1) Retrospective Review. The retrospective review must be completed within one hundred twenty (120) days of the determination of noncompliance. The retrospective review will be documented by the RCOI Administrator or designee. If bias is found in the course of the retrospective review, UF must promptly notify PHS and submit a mitigation report that addresses

the impact of the bias on the research and UF's plan of action to eliminate or mitigate the effect of the bias.

- 2) PHS-funded Clinical Research. In instances of non-compliance in PHS Clinical Research whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment, the Investigator is thereafter required to disclose the FCOI in each public presentation of the results of the relevant research and also request an addendum to previously published presentations of the relevant research.

V. Contact.

- A. Contact/Questions.** Any questions related to this policy should be directed to UF Research Integrity.