

Financial Conflict of Interest

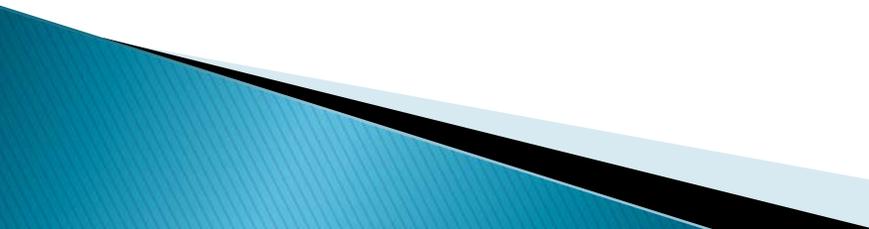
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What is a Conflict of Interest?

A conflict of interest in basic terms is described in University policy as a situation in which a person serves or represents two distinct entities (or persons) or must choose between two conflicting interests.

A "conflict of interest" in the traditional sense encompasses situations in which a person has actually neglected or breached a duty to one entity to the benefit of another, situations in which a person has used his or her position with one entity to advance personal gain or the gain of another entity, and situations in which there is a potential for breaching a duty to one entity. The latter is sometimes referred to as a "potential" or "apparent" conflict of interest. The term "conflict of interest" will be used to describe all these situations.

<http://www.generalcounsel.ufl.edu/downloads/COI.pdf>



A Conflict of Interest per University of Florida Rule 6C1-1.011 means:

- I. Any conflict between the private interests of the employee and the public interests of the University of Florida or the State of Florida, including conflicts of interest specified under Florida Statutes; or

 2. Any outside activity or financial interest which interferes with the full and faithful performance of the employee's professional or institutional responsibilities or obligations.
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Why Does the University Care About Conflicts of Interest?

1. Faculty and staff of the University must recognize their main responsibility is to the University. They may also engage in outside employment, consulting, and similar activities which aid the dissemination of knowledge and expertise developed at the University and advance the professional competence of faculty and staff. Thus, participation in outside activities often serves the mission of the University in addition to benefiting employees.

Such activities and financial interests are of concern if they result in conflicts with an employee's University duties. University policy allows faculty and staff to participate in outside activities and hold financial interests as long as they do not conflict with their duties.

2. All University employees are subject to the conflict interest provisions in the code of ethics of the State of Florida (Chapter 112, Part III, Florida Statutes) and the conflict of interest rules and policies of the University of Florida.

Additionally, investigators involved in federal research are subject to conflict of interest regulations applicable to Public Health Service and National Science Foundation projects.

3. The responsibility for adhering to the rules, policies and regulations on conflict of interest and outside activities rests with the individual faculty or staff member.

Basic Principles

- *The educational programs and professional careers of individual students and faculty members cannot be adversely affected by a faculty or staff member's outside activities or financial interests.*
 - *The university's research and education programs cannot be adversely affected and must remain credible. The outside activities of employees should not impede the dissemination of knowledge.*
 - *The university's personnel and resources must be used for the promotion of the mission of the university and the public interest rather than for private gain.*
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The following outside activities/financial interests provide a basis for a possible conflict of interest:

- 1) Outside activities which represent time commitments that would interfere with a faculty or staff member's accomplishing his or her university duties.
 - 2) Outside activities using equipment, personnel, or resources of the university.
 - 3) Outside activities where employees and students supervised by the employee are also involved.
 - 4) Outside activities (consulting, employment, management, etc) with a person or entity, or financial interests in an entity, that does business with the university.
 - 5) Outside activities or financial interests in an entity which competes with the University's activities, particularly when these are in the same field as that of the faculty or staff.
 - 6) Outside activities or financial interests in an entity that is supporting the faculty or staff member's research or training activities at the University.
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How Do I Get My Outside Activity or Financial Interest Approved?

A faculty (including faculty members paid through OPS funds) or staff member engaged in outside activities or holding a financial interest that must be reported is REQUIRED to complete the University's "Disclosure of Outside Activities and Financial Interests" form prior to the commencement of the outside activity or financial interest and thereafter at the beginning of each contractual year of employment. Disclosure is required of any faculty or staff member whether holding a fulltime or part-time appointment.

The link to the form is <http://www.aa.ufl.edu/Data/Sites/18/media/forms/outside-activity-form-in-unit-revised-070113.pdf> for faculty/staff in the collective bargain unit; for faculty/staff not in unit the form is <http://generalcounsel.ufl.edu/media/ufl.edu/content-assets/generalcounselufl.edu/documents/AppendixB2.pdf>

Do I have To Be Paid for A Conflict to Exist?

- ▶ Conflicts may arise even in instances in which the faculty or staff member will not receive any economic benefit from the outside activity. For example, a conflict is evident if a faculty member's obligations to the university in terms of teaching and advising are not met due to the time spent on the outside activity. The conflict exists even though the activity may provide no remuneration to the faculty member.
- ▶ <http://www.generalcounsel.ufl.edu/downloads/COI.pdf>

Federal Reporting Requirements relating to Sponsored Projects

- ▶ Federal regulations require that the university manage, reduce, or eliminate any actual or potential conflicts of interest that may be presented by certain compensated outside activities and financial interests of persons involved in sponsored research projects funded by the Public Health Service (PHS), those sponsors that follow PHS regulations (List can be found here: <http://research.ufl.edu/faculty-and-staff/research-compliance/conflict-of-interest-and-outside-activities/list-of-organizations-that-require-compliance-with-phs-regulations.html>) and the National Science Foundation (NSF).
- ▶ The primary purpose of the federal regulations is to prevent bias in the design, conduct, or reporting of research projects.
- ▶ All investigators working on projects funded by the PHS, AHA or the NSF must abide by these requirements.
- ▶ An “investigator” is defined as the principal investigator, co-principal investigator, or any other person responsible for the design, conduct, or reporting of the proposed or funded research.

Code of Ethics For State Of Florida Employees

- ▶ A faculty or staff of the University may not be employed by or have a contractual relationship with a company which is "doing business" with the University.
 - ▶ An Exemption is provided which allows a faculty or staff to be a consultant, employee or have an ownership interest in a company that licenses the faculty member's technology from the University. The exemption also allows a faculty member with an employment or contractual relationship with a company to work on a research contract between the university and the company.
 - ▶ However, such Exemptions are allowed only with prior review and approval.
 - ▶ The Exemption Law was passed to facilitate transfer of University developed technology to companies by making possible license agreements and research contracts with companies with which the faculty member-inventors have relationships.
 - ▶ The Exemption procedure is done through the Division of Research Compliance.
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Institutional Conflict of Interest

- ▶ An Institutional Conflict of Interest exists when the University holds equity in a company that licenses technology and/or supports ongoing research at the University.
 - ▶ When a research contract is entered into by the University with a company in which the University holds equity, or when a research project involves a licensed product of a company in which the University holds equity special attention is paid to resource allocation, employment practices, and graduate student assignments.
 - ▶ The University can only be involved in clinical trials/product testing of its licensed technology with the approval of the Vice President for Research.
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Institutional Conflict of Interest

- ▶ UFRF managers, which shall include its directors and officers, shall not acquire stock in any company which has provided the University with an equity position as consideration under a license or other agreement.
 - ▶ University department chairs and college administrators (deans, associate deans, assistant deans, and so forth) shall not acquire stock in any company when the respective department or college may benefit financially from the license or other agreement.
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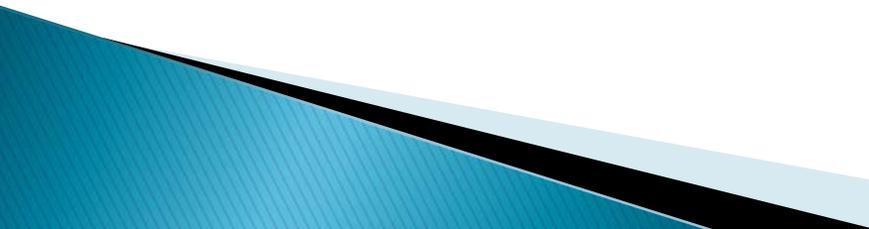
Investigator's Required Disclosure per NIH

- ▶ Under new NIH rules an investigator must disclose a Significant Financial Interest (SFI) related to their institutional responsibilities to the University using the new threshold amounts.
 1. For a publicly traded entity a SFI exists if the value of payments received for the prior 12 months **plus** the value of any equity exceeds \$5000.
 2. For a non-public entity a SFI exists if the value of payments received for the prior 12 months exceeds \$5000 **or** if the investigator holds any equity.
 3. Travel that is reimbursed or sponsored related to institutional responsibilities.

- ▶ An SFI does not include salary, royalties or other payments paid by the University to the investigator.
- ▶ Other federal agencies including NSF continue to use the thresholds of payments exceeding \$10,000 or equity exceeding \$10,000 or 5%.

- ▶ The link to the disclosure forms is <http://research.ufl.edu/faculty-and-staff/research-compliance/conflict-of-interest-and-outside-activities.html>

New NIH Rule - Process

- ▶ An investigator discloses a Significant Financial Interest (SFI).
 - ▶ The University reviews the disclosure to decide if the SFI is related to an NIH project and a conflict exists.
 - ▶ Related means when the SFI is affected by the project or the SFI is in an entity whose financial interests are affected by the project.
 - ▶ All investigators must receive financial conflict of interest training before engaging in the NIH research and every 4 years thereafter.
 - ▶ The University must develop a monitoring plan to manage the conflict.
 - ▶ The University must either post on a website, or respond in writing within 5 days, information about financial conflicts in NIH projects including the investigator's name, their research role, the nature of the SFI, and the dollar value of the SFI.
 - ▶ The university must report to the NIH on managed conflicts the value of the financial interest, the nature of the financial interest (equity, consulting fees etc), and key elements of the management plan.
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Questions

- ▶ 1. Is the following statement True or False? The simplest way to describe a potential conflict of interest is when a person serves two entities at the same time.
- ▶ The statement is True. Situations where a person has dual loyalties often result in a conflict of interest. In research if an investigator is a paid employee or owns stock in the company sponsoring the research bias may exist in the design, conduct or reporting of the research.

Questions

- ▶ 2. As a University of Florida employee would I have a conflict if a) my private interests interfered with the public interests of the University or if b) my outside activity such as consulting interfered with my ability to fulfill my University responsibilities?
 - ▶ A. a only.
 - ▶ B. b only.
 - ▶ C. Either a or b.
 - ▶ D. Neither a nor b.

- ▶ The answer is C.

Questions

- ▶ 3. Which of the following statements explains why the University cares about conflicts of interest ?
 - ▶ A. The University is interested in my personal business.
 - ▶ B. The University has a duty to ensure it's rules and state and federal regulations are complied with.
 - ▶ The answer is B.
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Questions

- ▶ 4. Is the following statement True or false? It is the responsibility of my chair/supervisor to make sure I adhere to the conflict of interest rules and regulations.
 - ▶ The statement is False. It is the responsibility of the individual faculty or staff member.
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Questions

- ▶ 5. Is the following statement True or False? The following are all situations which could be a conflict.
- ▶ A. An outside activity on which I spend a lot of hours and I do not get my UF work done.
- ▶ B. An outside activity involving a student I supervise at the University.
- ▶ C. An outside activity with an entity that does business with the University.
- ▶ D. An outside activity in which I am not being paid.

- ▶ The statement is True.

Questions

- ▶ 6. The following individuals are subject to University, state and federal conflict of interest regulations:
 - ▶ a. Principal Investigator.
 - ▶ b. Co-principal investigator.
 - ▶ c. Any person responsible for the design, conduct or reporting of the research.

- ▶ A. a only.
- ▶ B. b only.
- ▶ C. c only.
- ▶ D. a, b and c.
- ▶ E. Neither a, b nor c.

- ▶ The answer is D.

Questions

- ▶ 7. Under the Code of Ethics for State of Florida Employees a Request for Conflict Exemption is required when:
 - ▶ a. A person consults for or owns stock in a company and that company sponsors research at the University.
 - ▶ b. A person consults for or owns stock in a company and that company has a license agreement with the University.
 - ▶ c. A person consults for or owns stock in a company.

- ▶ A. a only.
- ▶ B. b only.
- ▶ C. c only.
- ▶ D. a, b and c.
- ▶ E. a and b only.
- ▶ F. Neither a, b nor c.

- ▶ The answer is E.

Questions

- ▶ 8. Which of the following are examples of a Significant Financial Interest (SFI) for NIH?
 - ▶ a. An investigator is paid \$6000 for consulting for the year.
 - ▶ b. An investigator owns \$6000 worth of stock in a publicly traded company.
 - ▶ c. An investigator is paid \$2000 for consulting and owns \$4000 worth of stock in a publicly traded company.

 - ▶ A. a only.
 - ▶ B. b only.
 - ▶ C. c only.
 - ▶ D. a, b and c.
 - ▶ E. a and b only.
 - ▶ F. Neither a, b nor c.
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- ▶ The answer is D. For a non-publicly traded company an SFI includes any equity interest.

Questions

- ▶ 9. Which of the following are examples of a Significant Financial Interest (SFI)?
- ▶ a. An investigator was paid \$4000 for consulting for the year for a non-publicly traded company.
- ▶ b. An investigator owns \$1 worth of stock in a non-publicly traded company.
- ▶ c. An investigator was paid \$10,000 for the year from the University as royalties for an invention he created.

- ▶ A. a only.
- ▶ B. b only.
- ▶ C. c only.
- ▶ D. a, b c and d.
- ▶ E. b and d only.
- ▶ F. Neither a, b nor c.

- ▶ The answer is B. Royalties from the University are not included in SFI.

Questions

- ▶ 10. Which of the following are required under the new NIH rule?
- ▶ a. The University reviews investigator disclosures to decide if a Significant Financial Interest (SFI) is related to an NIH project and a conflict exists.
- ▶ b. The University must develop a monitoring plan to manage a conflict.
- ▶ c. The University must post on a public website or respond in writing within 5 days concerning information about conflicts.

- ▶ A. a only.
- ▶ B. b only.
- ▶ C. c only.
- ▶ D. a, b and c.
- ▶ E. a and b only.
- ▶ F. Neither a, b nor c.

- ▶ The answer is D.