

<b>SUBJECT:</b> Reporting a Potential Conflict of Interest or Conflict of Commitment in Research	<b>Effective Date:</b> 08-20-12	<b>Policy Number:</b> 4-504.2	
	<b>Supersedes:</b> 4-504, 4-504.1	<b>Page</b> 1	<b>Of</b> 7
	<b>Responsible Authority:</b> Vice President for Research & Commercialization		

DATES OF INITIAL ADOPTION AND EFFECTIVE DATES: 2-18-08, 9-29-08

#### APPLICABILITY/ACCOUNTABILITY

This policy applies to all university faculty members, Executive Service employees, postdoctoral associates, Administrative and Professional employees, University Support Personnel System employees, Other Personnel Support employees, and students engaged in both sponsored and non-sponsored research.

#### PREAMBLE

As a part of UCF's academic and research mission, the university encourages its employees to participate in sponsored research, consulting, and other activities that benefit the university, participants, affiliates, and the public at large. In doing so, UCF employees are obligated to act in the best interest of the university and to ensure that outside activities or outside financial interests do not interfere with their obligation to the university. The existence of trust from the public and from the scientific community is paramount to the successful advancement of knowledge and the growth of the university's academic and research programs. In addition to the university's expectation that research be conducted with the highest ethical standards and professional integrity, federal laws and state statutes regulate conflicts of interest and establish related ethical and integrity standards. This policy establishes a process to comply with these regulations and statutes.

#### BACKGROUND

Federal regulations and state statutes require institutions of higher education to bear primary responsibility for employees and affiliates to disclose conflicts of commitment, outside activity, and potential financial conflicts of interest. The university has the responsibility to establish Conflict of interest policies and procedures to provide appropriate safeguards to protect the interests of the

university and sponsored agencies, and to effectively communicate to faculty members, employees, students, and affiliates the university's conflict of interest and commitment policies and procedures.

## POLICY STATEMENT

University faculty members, Executive Service employees, postdoctoral associates, Administrative and Professional employees, University Support Personnel System employees, Other Personnel Support employees, and affiliates engaged in both sponsored and non-sponsored research, must disclose conflicts of commitment, outside activity, and financial conflicts of interest to designated officials. All university employees (including students) and affiliates planning to participate in or are participating in sponsored and non-sponsored research activity must comply with federal regulations and state statutes in regard to disclosing, managing, and reporting significant financial interests. All employees engaging in research must annually or within 30 days of discovering, acquiring, or committing to a new financial interest or commitment, report potential conflicts of interest or commitment, or the appearance of a conflict. University faculty members, Executive Service employees, postdoctoral associates, Administrative and Professional employees, University Support Personnel System employees, Other Personnel Support employees, and affiliates responsible for the design, conduct, or reporting of research must complete conflict of interest training prior to engaging in research. Training must occur at least once every four years or sooner if an applicable change occurs.

The Office of Research & Commercialization is charged with oversight of the conflict of interest and commitment program for research and is responsible for applicable policies, procedures, guidelines, and training to communicate the program requirements. In addition, the Office of Research & Commercialization is responsible for the review of disclosures and, when applicable, the review and approval of monitoring and management plans.

The University Compliance, Ethics, and Risk Office is charged with the oversight of the academic conflict of interest and commitment program.

## DEFINITIONS

**Conflict of Interest.** A divergence between an individual's private interests and his or her employment obligations to the university such that an independent observer may reasonably question whether the individual's actions or decisions are influenced or determined by considerations other than the best interest of the university.

**Conflict of Commitment.** An employee's devotion of time to activities that adversely affect his or her capability to meet their primary university responsibilities. Examples may include but are not limited to outside employment, *pro bono* or volunteer work, and government service in the public interest.

**Outside Activity or Employment.** Any compensated or uncompensated secondary employment or activity, private practice, private consulting, teaching, research, or other activity that is not part of the employee's assigned duties at the university.

**Financial Conflict of Interest.** A significant financial interest that could directly and significantly affect the design, conduct, or reporting of sponsored and non-sponsored research.

**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 sponsored and non-sponsored research. The term includes key personnel, collaborators, or consultants who are responsible for the design, conduct, or reporting of sponsored and non-sponsored research.

**Institutional Responsibilities.** An investigator's professional responsibilities on behalf of the university. The activities outlined in an employee's annual assignment or position description may include administration, teaching, research and creative activities, course preparation, curriculum development, lectures, evaluation of student efforts, academic advising, committee meetings and memberships, service on panels such as university review boards or data and safety monitoring boards, public service to include service on advisory committee's or review panels, and any other activity assigned by the employee's supervisor in accordance with university policies.

**Manage.** Taking action to address a financial conflict of interest, which can include reducing or eliminating the significant financial interest to ensure, to the extent possible, that the design, conduct, and reporting of research will be free from bias or personal financial gain.

**Research.** A systematic experiment, study, demonstration, or survey designed to develop or contribute general knowledge (basic research) or specific knowledge (applied research) in all fields by establishing, discovering, developing, elucidating, or confirming engineering, science, medicine, education, mathematics, humanities, and research involving human subjects or animals. The term includes product development to include a diagnostic test or drug.

**Affiliate.** A compensated or uncompensated subcontractor, sub-recipient, consultant, or other third-party entity performing research services for the university under a written or verbal agreement.

#### **Significant Financial Interest**

(1) A financial interest consisting of one or more of the following interests of the investigator (and those of the investigator's spouse and dependent children) that reasonably appears to be related to the investigator's university (institutional) responsibilities.

(i) with regard to any publicly traded entity, a significant financial interest exists if the value of any remuneration received from the entity in the 12 months preceding the disclosure and the value of any equity interest or fixed asset value of the entity as of the date of disclosure, when aggregated, equals or exceeds \$5,000;

(ii) with regard to any non-publically traded entity, a significant financial interest exists if the value of any remuneration received from the entity in the 12 months preceding the disclosure, when aggregated, equals or exceeds \$5,000 or when the investigator (or the investigator's spouse and dependent children) holds any equity interest (e.g., stock, stock options, or other ownership interest); or (iii) intellectual property rights and interests (e.g., patents, copyrights, trademarks) upon receipt of income related to such rights and interests.

(2) The occurrence of any reimbursed travel (i.e., that which is paid on behalf of the investigator and not reimbursed to the investigator) related to the investigator's institutional responsibilities. This disclosure requirement does not apply to travel that is reimbursed or sponsored by a federal, state, or local government agency, or is funded through a sponsored contract or grant through the Office of Research & Commercialization.

(3) The term significant financial interest does not include the following:

(i) salary, royalties, or other remuneration paid by the university,

(ii) 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 the university,

(iii) income from service on advisory committees, review panels for a federal, state, or local government agency, institution of higher education, an academic teaching hospital, medical center, or research institute affiliated with the university.

## PROCEDURE

### Disclosure:

Faculty, Executive Service employees, and postdoctoral employees participating in or planning to participate in sponsored and non-sponsored research activity must complete the Potential Outside Activity, Employment, and Conflict of Interest and Commitment Disclosure Report (Form AA-21) on an annual basis and within 30 days of discovering, acquiring, or committing to a new financial interest or commitment.

Administrative and Professional employees, University Support Personnel System employees, Other Personnel Support employees, adjunct faculty, students, and affiliates planning to participate in or who are participating in sponsored and non-sponsored research activity must complete the Potential Outside

Activity, Employment, and Conflict of Interest and Commitment Report (Form ORC-COI) on an annual basis and within 30 days of discovering, acquiring, or committing to a new financial interest or commitment.

The Office of Research & Commercialization in conjunction with the University Compliance, Ethics, and Risk Office will review disclosures. Disclosures containing actual or potential conflicts of interest will be reviewed by the conflict of interest committee. The conflict of interest committee will determine if a management plan or other action is necessary.

#### Training:

The Office of Research & Commercialization will provide conflict of interest training modules to investigators. Investigators are required to complete conflict of interest training prior to engaging in research at least every four years, and within a thirty day period if one or more of the following occur: 1) the university revises its conflict of interest policies, 2) an investigator is new to the university, and 3) the university finds that an investigator is not in compliance with the university's conflict of interest policy and procedures.

#### Reporting Conflict of Interests to Sponsors:

The Office of Research & Commercialization is responsible for reporting investigator's significant financial interests to sponsors in accordance with sponsors' regulations and their policies and procedures, to include annual reports, changes to management or mitigation plans, and retrospective reports. Investigators will provide sufficient data to the Office of Research & Commercialization and other designated university officials to report the nature and extent of the financial conflict.

#### Records:

The Office of Research & Commercialization is responsible for maintaining records relating to all investigator conflict of interest disclosures, the university's review and response to such disclosures, and all actions taken by the university in accordance with its policy and procedures for three years from the date the final expenditure report is submitted to the sponsor.

#### Noncompliance:

Failure by an investigator to comply with the university's financial conflicts of interest policy or a financial conflict of interest management or mitigation plan will result in disciplinary action up to and including termination for just cause.

#### Subrecipients and other Affiliates:

The Office of Research & Commercialization will incorporate for subrecipients (includes affiliates) terms that establish whether the financial conflict of interest policy of the university or that of the subrecipients will apply to the subrecipients' investigators. Subrecipients shall certify as a part of the agreement that their conflict of interest policies adhere to the university's conflict of interest policy.

If the subrecipient does not have a conflict of interest policy that meets or exceeds the university's conflict of interest policy, the subrecipient investigators must be subject to the university's financial conflict of interest policy.

**Public Accessibility:**

The university will post the conflict of interest policy and procedure as well as corresponding conflict of interest guidelines on a publically accessible

Web site. When an investigator's significant financial interest is still held by the investigator and the conflict of interest committee determines the significant financial interest is related to the investigators sponsored research, the Office of Research & Commercialization will post the following information on a publically accessible Web site: 1) the investigator's name, title and research project role, 2) the name of the entity in which the significant financial interest is held, 3) the nature of the significant financial interest, and 4) the approximate dollar value of the significant financial interest (within dollar ranges).

**RELATED INFORMATION**

- 1) National Institutes of Health Grants Policy Statement, Part II, Terms and Conditions of NIH Grant Awards, Subpart A: General, Chapter 4.1.10, and Financial Conflict of Interest
- 2) National Science Foundation Award Administrative Guide, Chapter IV-Grantee Standards, Part A
- 3) State of Florida Code of Ethics for Public Officers and Employees - Florida Statutes, Title X, Chapter 112.313 - 112.326
- 4) UCF Regulation - UCF-3.018, Conflict of Interest or Commitment; Outside Activity or Employment

**RELATED DOCUMENTS**

- 1) Public Health Service Conflict of Interest Regulations - Title 42, CFR Part 50 and 45 CFR Part 94
- 2) National Science Foundation Conflict of Interest Regulations - Title 45, Part 680
- 3) Food and Drug Administration Regulations-Financial Disclosure by Clinical Investigators - 21 CFR, Part 54
- 4) UCF BOT-UFF Collective Bargaining Agreement
- 5) UCF Golden Rule Student Handbook

RELATED UCF WEB SITES

<http://www.research.ucf.edu/compliance>

<http://compliance.ucf.edu/conflict-of-interest/>

FORMS

- 1) AA21 - Potential Outside Activity, Employment, and Conflict of Interest and Commitment Report (faculty, executive staff, and post-doctoral employees)
- 2) ORC-COI - Potential Outside Activity, Employment, and Conflict of Interest and Commitment Report (A&P, USPS, OPS (to include adjunct faculty)
- 3) HR-11 - Report of Potential Conflict of Interest, Outside Activity and Employment for A&P or USPS Employees
- 4) HR-12 - Use of University Personnel, Equipment, Facilities, Students, or Services

INITIATING AUTHORITY

Vice President for Research & Commercialization

POLICY APPROVAL (For use by the Office of the President)	
Policy Number: 4-504.2	
Initiating Authority: <u>[Signature]</u>	Date: <u>8-20-12</u>
Policies and Procedures Review Committee Chair: <u>[Signature]</u>	Date: <u>8-20-12</u>
President or Designee: <u>[Signature]</u>	Date: <u>8/20/12</u>