COI Definitions

Affiliate

Refers to a compensated or uncompensated subcontractor, sub-recipient, consultant, or other third-party entity performing sponsored research services for the university under a written or verbal agreement. See *UCF Policy 4-504*.

Collective Bargaining Agreement

The Collective Bargaining Agreement (CBA), Article 19 contains the following definitions:

- (a) "Outside Activity" shall mean any private practice, private consulting, additional teaching or research, or other personal commitment, e.g., service on a Board of Directors, participation in a civic or charitable organization, political activity, etc., whether compensated or uncompensated, that is not part of the employee's assigned duties and for which the University provides no compensation.
- (b) "Conflict of Interest" shall mean: (1) any conflict between the private interests of the employee and the public interests of the University, the Board of Governors, or the State of Florida, including conflicts of interest specified under Florida Statutes; or (2) any activity that interferes with the full performance of the employee's professional or institutional responsibilities or obligations.
- (c) "Conflict of Commitment" shall mean: (1) outside activities that involve frequent or prolonged absences from the University on non-University business; or (2) outside activities that engage a substantial portion of the time an employee is expected to spend on assigned duties or University-related activities.

Conflict of Commitment

Conflict of Commitment means an employee's devotion of time to activities that adversely affect their 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. See UCF Policy 4-504.

Conflict of Interest

Conflict of Interest means a divergence between an individual's private interests and their employment or service 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. *See UCF Policy 4-504.*

Covered clinical study

Covered clinical study means any study of a drug or device in humans submitted in a marketing application or reclassification petition subject to this part that the applicant or FDA relies on to establish that the product is effective (including studies that show equivalence to an effective product) or any study in which a single investigator makes a significant contribution to the demonstration of safety. This would, in general, not include phase I tolerance studies or pharmacokinetic studies, most clinical pharmacology studies (unless they are critical to an efficacy determination), large open safety studies conducted at multiple sites, treatment protocols, and parallel track protocols. An applicant may consult with FDA as to which clinical studies constitute "covered clinical studies" for purposes of complying with financial disclosure requirements. See 21 CFR Part 54, Financial Disclosure by Clinical Investigators.

Entity

<u>Business entity:</u> means any corporation, partnership, limited partnership, company, limited liability company, proprietorship, firm, enterprise, franchise, association, self-employed individual, or trust, whether fictitiously named or not, doing business in this state. *See FL. Statute 112.312(5).*

Federal Guidelines

Federal Conflict of Interest Criteria

A potential conflict of interest exists when a faculty member's significant financial interest (anything of monetary value including salary, equity interests, and/or intellectual property rights) could directly and significantly affect the design, conduct or reporting of the research. See <u>Department of Health and Human Services 42 CFR Part 50 and 45 CFR Part 94 Final Rule</u>, <u>Financial Disclosures by Clinical Investigators 21 CFR Part 54</u>, and <u>National Science Foundation Proposal & Award Policies & Procedures Guide</u>, <u>Part 2</u>, <u>Chapter IX</u>.

Under sponsored federal programs the potential conflict is between the investigator's personal financial interests and their ability to perform objective research.

Florida Statute and UCF Regulation

Conflict of Interest Criteria

Florida statutes (112.311) requires that no employee shall have any interest, financial or otherwise, direct or indirect; engage in any business transaction or professional activity; or incur any obligation of any nature which is in substantial conflict with the proper discharge of his or her duties in the public interest.

Florida Standards of Conduct (FL. Statute 112.313)

The State of Florida outlines standards of conduct for public officers and employees that are also contained in University Regulation UCF-3.018 Conflict of Interest or Commitment; Outside Activity or Employment. Three of the standards apply to outside activity that may create a conflict of interest. To assist with your review the three standards have been summarized within the context of university employment.

1. Doing business with the university (See FL. Statute 112.313(3))

A university employee acting in their official capacity cannot directly or indirectly purchase, rent, or lease any realty, goods, or services for the university from any entity of which the employee (or employee's spouse or child) serves as an officer, partner, director, or proprietor, or owns more than a 5% interest.

A university employee acting in their private capacity cannot rent, lease, or sell any realty, goods, or services to the university.

2. Unauthorized Compensation (See FL. Statute 112.313(4))

A university employee (or employee's spouse or minor child) cannot accept any compensation, payment, or thing of value when they know or should know, that it (compensation, payment or thing of value) is given to influence the employee's actions in his or her employment capacity.

3. Conflicting Employment or Contractual Relationship (See FL. Statute 112.313(7))

A university employee cannot work for or contract with a business entity that sells or purchases goods or services from the university. A university employee may not work for or have a contractual arrangement which will impede the full and faithful discharge of his or her public duties. A university employee may not create a continuing or frequently recurring conflict between his or her private interests and the performance of his or her public duties.

Under Florida State statute the potential conflict is between the employee's private financial interests and their public responsibilities to the State.

FL Statute Exemptions 112.313(12)(a) - (j)

Visit the Florida Statute 112.313 web page to review the exemptions.

Immediate Family

For purposes of outside activity and potential conflict of interest and commitment reporting, immediate family shall refer to the investigator's spouse and children (dependent or independent).

Institutional Responsibilities

Refers to 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 committees or review panels, and any other activity assigned by the employee's supervisor in accordance with university policies. See UCF Policy 4-504.

Investigator

Investigator means the project director (PD) or principal investigator (PI), co-investigator, key personnel, and any other person, regardless of title, position or employment status, who is responsible for the design, conduct, or reporting of sponsored research. The term includes key personnel, collaborators, or consultants who are responsible for the design, conduct, or reporting of sponsored research. *See UCF Policy 4-504*.

Outside Activity

Outside Activity means 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. *See UCF Policy 4-504*.

Political Office

See <u>FL Statute 104.31</u> for information regarding political activities of state employees.

Potential Conflicts of Interest and Commitment

<u>UCF Collective Bargaining Agreement, Article 19.3 Conflicts of Interest/Commitment Prohibited.</u>
Unmitigated conflicts of interest and commitment, including those arising from University or outside activities, are prohibited. Employees are responsible for reporting and resolving such conflicts of interest or commitment, working in conjunction with their supervisors and other University officials.

Eight-hour Statement

Although not a part of the official conflict of commitment definition, please note that there is no "eighthour rule" stating how much time a person can spend on activity outside of their current obligation to the university. If the amount of time spent on paid or unpaid activities outside the university interferes with one's teaching, research, or service work for UCF, it is a conflict of commitment.

Relative

A relative is anyone related to an employee in the following ways, and includes those within these categories who are referred to as adopted, step-, foster, grand-, half-, in-law, spouse of, or:

- Parent
- Child
- Sibling
- Uncle or aunt
- First cousin
- Nephew or niece
- Spouse, domestic partner

Persons who intend to marry or with whom the employee intends to form a domestic partnership or other intimate relationship are also included in this definition of relative. See UCF Policy 3-008.

Remuneration

This term includes salary and any payment for services not otherwise identified as salary (e.g. consulting fees, honoraria, paid authorship. See 42 CFR Part 50.

Research

Research means 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 training, public service, and product development to include a diagnostic test or drug. *See UCF Policy 4-504.*

Significant Financial Interest (see UCF Policy 4.504)

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.

- 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;
- with regard to any non-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, 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
- 3. intellectual property rights and interests (e.g., patents, copyrights, trademarks), upon receipt of income related to such rights and interests.
- 4. 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. 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 is excluded.

Supervisory Relationship

Exists when a relative is directly or indirectly, through span of control, responsible for supervising, directing, evaluating, or influencing the work activities, or job performance of another relative, or is in the same chain of command of the relative. *See UCF Policy 3-008*.