

Reporting Outside Activities, Financial Interests, and Potential Conflicts of Interest or Conflicts of Commitment in Research

Policy Number 4-504.3

Responsible Authority Director, Office of Compliance, Office of Research and Assistant

Vice President for Compliance and Ethics

Initiating Authority Vice President for Compliance and Ethics

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 2/26/2021

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 2/18/2008

APPLICABILITY/ACCOUNTABILITY

This policy applies to all university faculty, staff, student employees, and affiliates engaged in university research.

BACKGROUND INFORMATION

As a part of the University of Central Florida's academic and research mission, the university encourages its employees to participate in 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.

Federal regulations and state statutes require institutions of higher education to bear primary

responsibility for employees and affiliates to disclose outside activities, financial interests, and potential conflicts of interests and conflicts of commitment. 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, staff, student employees, and affiliates the university's conflict of interest and commitment policies and procedures.

Additionally, in recent years higher education institutions in the United States, including Florida universities and academic medical centers, have been the targets of foreign governments which have led to intellectual property theft and advanced technology transfers. In response to this threat, the Florida House of Representatives created the Select Committee on the Integrity of Research Institutions and launched a probe into Florida taxpayer-supported research institutions' vulnerabilities. Resulting from the work of this committee, and with the purpose of ensuring that Florida's public postsecondary institutions are accurately reporting all sources of research support, financial interests and affiliations, on July 1, 2020, Florida Statutes Section 1012.977 became effective. This section of statute requires that all persons employed by a state university engaging in research which was created or authorized pursuant to part II of chapter 1004, consents to the policies of the university or entity, the regulations of the Board of Governors, and the laws of this state. At a minimum, such policies shall require employees engaged in the design, conduct, or reporting of research to disclose and receive a determination that the outside activity or financial interest of the employee does not affect the integrity of the state university or entity. The statute provides that an employee engaged in the design, conduct, or reporting of research who fails to disclose any outside activity or financial interest as defined by the statute shall be suspended without pay pending the outcome of an investigation which shall not exceed 60 days. Upon conclusion of the investigation, the university or entity may terminate the contract of the employee.

POLICY STATEMENT

All employees and affiliates engaged in university research must comply with federal regulations, state statutes, and university regulations and policies in regard to disclosing, managing, and reporting outside activities and financial interests. Employees engaged in the design, conduct, or reporting of research are required to disclose applicable financial interests and outside activities and receive a determination by the university that the outside activity or financial interest does not affect the integrity of the university.

Outside activities and financial interests subject to reporting must be disclosed annually and throughout the year as circumstances change prior to committing to the new financial interest or outside activity. Newly acquired or discovered financial interests (e.g., through purchase, marriage, or inheritance) must be disclosed within 30-days.

Employees are prohibited from directly or indirectly authorizing business transactions related to university sponsored programs or technology transfer with an entity where they hold an employment or contractual relationship, ownership, or other financial interest without an executed Conflict of Interest Exemption under Florida Statutes 112.313(12)(h) approved by the

university president and Chair of the university Board of Trustees. Exemptions require full disclosure of the proposed transaction/relationship in advance and must be approved prior to beginning the activity.

Prior to submitting research applications to sponsors, investigators must ensure that a completed annual disclosure form for the corresponding academic year has been submitted. Investigators must disclose significant financial interests related to a sponsored research proposal, human subjects research protocol, and institutional animal care and use protocol at the time of application. Additionally, investigators 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.

If an investigator engages in university research through a subrecipient agreement and does not have a conflict of interest policy that is compliant with federal regulations and the sponsoring terms and conditions require a conflict of interest policy, the affiliate investigator is subject to university policy.

The Office of Research, Compliance Office is responsible for the sponsored research conflict of interest program and for applicable policies, procedures, guidelines, and training to communicate the program requirements. In addition, the Office of Research, Compliance Office is responsible for the review of sponsored research related disclosures and, when applicable, the review and approval of monitoring and management plans.

University Compliance and Ethics is charged with oversight of the university's conflict of interest and commitment program.

Noncompliance

The University of Central Florida encourages its employees to participate in research, consulting, and other activities that benefit the university, participants, affiliates, and the public at large. Disclosing this activity fosters UCF's support of these efforts. However, failure by an employee to comply with this policy or a conflict of interest monitoring or management plan may result in disciplinary action up to and including termination for just cause. In accordance with Florida Statutes Section 1012.977 which became effective on July 1, 2020, any employee engaged in the design, conduct, or reporting of research who failed to disclose an outside activity related to their UCF area of expertise or a financial interest with a foreign entity shall be suspended without pay pending the outcome of an investigation which shall not exceed 60 days. Upon conclusion of the investigation, the university may terminate the contract of the employee.

DEFINITIONS

Affiliate. 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.

Conflict of Commitment. 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.

Conflict of Interest. 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.

Financial Conflict of Interest. A significant financial interest that could directly and significantly affect the design, conduct, or reporting of sponsored research and research involving human subjects and animals.

Financial Interest. Anything of value other than that provided directly by the university.

Foreign Entity. Includes: 1) a non-U.S. government, university, or company; or 2) an individual who is physically located outside of the U.S.

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.

Investigator. The project director or principal investigator, 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.

Monitoring and Management Plan. A plan 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.

Outside Activity. 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.

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 training, public service, and product development to include a diagnostic test or drug.

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.
 - a. 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;
 - b. 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 (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.
- 3. The term significant financial interest does not include the following:
 - a. salary, royalties, or other remuneration paid by the university,
 - 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,
 - c. 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.

Sponsored Research. Research executed by university employees using any university space, facilities, materials, equipment, or property which is financed by contract payments, grants or gifts from any source (<u>UCF Regulation UCF-2.027</u>). Sponsored research supports research and development, but it also includes instruction, training, professional development, curriculum development, community and public service projects, and commercialization. Sponsored research funding instruments also includes cooperative agreement, consortium agreement, and donation.

UCF Area of Expertise. The disclosers field or discipline in which the discloser conducts research, teaches, and/or provides service activities for UCF.

PROCEDURES

Annual Disclosure and Amendments

Faculty, staff, and student employees engaged in research must submit an online Potential Outside Activity, Employment, and Conflict of Interest and Commitment Disclosure (AA-21) through the university designated reporting system on an annual basis and throughout the year, submit an Amendment to the disclosure in advance of committing to a new outside activity or financial interest subject to AA-21 reporting. Newly acquired or discovered financial interests (e.g., through purchase, marriage, or inheritance) subject to AA-21 reporting must be submitted within 30-days.

Disclosures of outside activities and financial interests related to sponsored research are routed to the Office of Research, Compliance Office after supervisory review.

The Office of Research, Compliance Office will escalate disclosures containing actual or potential conflicts of interest related to sponsored research to the Research Conflict of Interest Committee for review. The Research Conflict of Interest Committee will determine if a monitoring and management plan or other action is necessary.

University Compliance and Ethics conducts the final review of all disclosures containing outside activities and financial interests.

Project Specific Financial Interest Disclosure

Investigators applying for sponsored research or Institutional Review Board (IRB) approval, must complete the project specific Financial Interest Disclosure section with each proposal through the university's designated research enterprise management system. The Office of Research, Compliance Office will review the project specific disclosures to determine whether they are considered a significant financial interest requiring review by the Research Conflict of Interest Committee. Financial interests reported in project specific disclosures must also be reported in the online Potential Outside Activity, Employment, and Conflict of Interest and Commitment Disclosure (AA-21) if not previously reported during the annual reporting period. The university considers investigators to be responsible for the design, conduct and/or reporting of the research and must complete the project specific Financial Interest Disclosure section with each proposal through the university's research enterprise management system.

Training

The Office of Research, Compliance Office will provide conflict of interest training modules to investigators. Investigators are required to complete conflict of interest training prior to engaging in sponsored 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, Compliance Office is responsible for reporting identified financial conflicts of interests held by investigators 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, Compliance Office and other designated university officials to report the nature and extent of the financial conflict.

Records

The Office of Research, Compliance Office 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.

Affiliates

The Office of Research will incorporate terms for affiliates that establish whether the conflict of interest policy of the university or that of the affiliate's institution will apply as dictated in federal agency guidelines.

Public Accessibility

When the Research Conflict of Interest Committee determines a significant financial interest is related to an investigator's Public Health Service (PHS) funded research, determines the significant financial interest is a financial conflict of interest, and the investigator still holds the significant financial interest, the University, through the Office of Research will ensure the following information is publicly accessible by a written response within five business days of a request:

- 1) the researcher'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) or a statement that a value cannot be readily determined.

Failure to Disclose

The following outlines the procedures that the Office of Research, Compliance Office and University Compliance and Ethics will follow to address compliance with Florida Statutes Section 1012.977.

- A. Submission of the *UCF Potential Outside Activity, Employment, and Conflict of Interest and Commitment Disclosure (AA-21)*
 - 1. At the start of the academic year, employees identified as engaged in the design, conduct, or reporting of research will receive an email with a link to submit an online AA-

- 21. From the time of receipt of the email invitation, the employee will have 30-days to submit applicable outside activities and financial interests.
- 2. Employees will receive a series of automated email reminders until the disclosure is submitted.
- 3. Should an employee fail to submit the AA-21 by the deadline, University Compliance and Ethics initiate the office's follow up process that includes coordination with deans and directors through their designated COI coordinators, direct emails to employees with copies to their supervisors, and providing a delinquent list to the provost's office for follow up and action.
- 4. After 90 days (60 days delinquent), the employee is considered to have failed to complete the annual process prompting an inquiry by University Compliance and Ethics.
- 5. In the absence of a current AA-21, the office will review the employee's previous years' AA-21 disclosures, when available, to conduct a foreign influence red flag review.
- 6. If a foreign influence red flag is identified University Compliance and Ethics, the Office of Research, Compliance Office, and the Office of Export Controls Compliance will perform an inquiry.
- 7. If the office does not identify a foreign influence red flag, it will follow the usual process working with the provost's office to obtain compliance with submitting the annual disclosure.

B. Outside activities or financial interests not disclosed on the AA-21

- 1. During the academic year if University Compliance and Ethics or the Office of Research, Compliance Office become aware of an outside activity related to the employee's UCF area of expertise or a financial interest with a foreign entity that an employee who is engaged in the design, conduct, or reporting of research was required to disclose but failed to disclose on the AA-21, the offices will notify the employee by email to immediately update or amend their existing AA-21.
- 2. If during an inquiry or investigation it is identified that an employee failed to disclose an outside activity related to the employee's UCF area of expertise or a financial interest with a foreign entity that they were required to disclose, the offices will evaluate the non-disclosure and integrate the request for appropriate disclosure during the process. Timing of requesting disclosure will align with the inquiry or investigation.
- 3. Upon receipt of the updated or amended AA-21, the offices will conduct a review to determine whether the activity qualifies as a foreign influence red flag.
- 4. If a foreign influence red flag is identified, the offices will perform an inquiry.

C. Inquiry and Investigation

- 1. If during the inquiry phase of a <u>foreign influence red flag review, evidence supports</u> <u>potential misconduct, then an investigation will commence.</u>
- 2. The employee who failed to initially disclose an outside activity related to the employee's UCF area of expertise or a financial interest with a foreign entity that they were required to disclose, will be suspended without pay pending the outcome of the investigation as required by Florida Statutes Section 1012.977.

- 3. The investigation shall last no longer than 60 days.
- 4. At the conclusion of the investigation, University Compliance and Ethics will issue findings and where appropriate, corrective action including disciplinary action up to and including termination.

RELATED INFORMATION or DOCUMENTS

- 1. <u>UCF Regulation-3.018 Conflict of Interest or Commitment; Outside Activity or Employment</u>
- 2. <u>UCF Regulation-4.029 Use of University Facilities; Definition; Priority of Use; Restrictions</u> on Use
- 3. UCF Research Conflict of Interest Committee Charter
- 4. UCF Collective Bargaining Agreement
- 5. UCF Graduate Student Handbook
- 6. UCF College of Medicine Faculty Handbook
- 7. UCF Policy 3-008.2 Employment of Relatives
- 8. <u>National Institutes of Health Grants Policy Statement, Part II, Terms and Conditions of NIH</u>
 <u>Grant Awards, Subpart A: General, Chapter 4.1.10, and Financial Conflict of Interest</u>
- 9. <u>The National Science Foundation Proposal and Award Policies and Procedures Guide, Chapter IX-Grantee Standards, Part A. Conflict of Interest Policies</u>
- 10. Florida Statutes Title X, Part III Code of Ethics for Public Officers and Employees Chapter 112.313 112.326
- 11. Florida Statutes Title XLVIII Chapter 1012 Section 1012.977
- 12. Department of Health and Human Services 42 CFR Part 50 and 45 CFR Part 94 Final Rule
- 13. <u>Food and Drug Administration Department of Health and Human Services Financial</u>
 Disclosure by Clinical Investigators 21 CFR, Part 54
- 14. <u>Potential Outside Activity, Employment, and Conflict of Interest and Commitment Disclosure</u> (AA-21)
- 15. Outside Activity, Financial Interest, and Potential Conflict Disclosure Matrix
- 16. Reporting Outside Activities, Financial Interests, and Potential Conflicts Guidance Document

CONTACTS

Office of Research, Compliance Office

Phone: (407) 823-3778 Email: COI@ucf.edu

Research Conflict of Interest Website

University Compliance and Ethics

Email: PCA@ucf.edu

University Compliance and Ethics Conflicts of Interest and Commitment Website

| POLICY APPROVAL (For use by the Office of the President) | |
|---|-------|
| Policy Number: 4-504.3 | |
| Initiating Authority and University Policies and Procedures Committee Chair: Alexander Cartwright Digitally signed by Alexander Cartwright Date: 2021.02.26 16:39:46-05'00' | Date: |