UNIVERSITY OF FLORIDA
GUIDELINES, POLICIES, AND PROCEDURES
ON CONFLICT OF INTEREST AND OUTSIDE ACTIVITIES,
INCLUDING FINANCIAL INTERESTS

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I. INTRODUCTION

The mission of the University of Florida is education, and central to that mission are teaching, research, and service. The university is committed to providing its students, as well as its public constituencies, the best instruction and other educational services possible. Research, encompassing all areas of academic inquiry and creativity at the university, is vital to the university's mission as it makes possible the expansion and advancement of knowledge. The faculty and staff members of the university must be committed to the university's goals of teaching, research, and service and recognize that their primary professional responsibility is to the university.

Employees of the University of Florida may also engage in outside employment, consulting, and other similar activities. These activities further the dissemination and use of the knowledge and expertise developed at the university and may also advance the professional competence and reputation of the faculty and staff members. Thus, participation in outside activities may often serve the mission of the university in addition to benefitting individual employees. Such activities and the financial interests of faculty and staff members are, however, of concern to the university if they result in conflicts with the employees' duties and responsibilities to the institution.

In recent years, governmental and other entities have increasingly encouraged colleges and universities to pursue research leading to new products and processes and then to develop such new products, often in conjunction with the institution's own licensing program. Faculty members and other employees may be encouraged to participate as consultants, employees, managers, and owners of companies to which the new technology is licensed. The university may conduct further research on the technology through the efforts of the same faculty members or other employees. These activities increase the potential for conflicts of interest and have caused greater emphasis to be placed on problems associated with such conflicts.

Issues involving conflicts of interest and outside activities in the college and university setting, however, are not new, nor are they confined to areas involving research or technology transfer. There are, in fact, a multiplicity of rules, regulations and laws that must be taken into account in the area of conflict of interest and outside activities. For example, as state employees, the faculty and staff of the University of Florida are bound by the State of Florida's statutory Code of Ethics for Public Employees. The University of Florida Board of Trustees also has promulgated regulations and has entered into collective bargaining agreements dealing with outside activities and conflicts of interest. This document outlines the problems and concerns presented by the conflicts of interest and outside activities of the university's faculty and staff (chapter II) as well as the university's procedures, including federal grant requirements (chapter III), and the state law (chapter IV) dealing with these matters.
II. BASIC PRINCIPLES OF CONFLICT OF INTEREST WITH REGARD TO OUTSIDE ACTIVITIES AND FINANCIAL INTERESTS

A "conflict of interest" occurs in any 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. In this document the term "conflict of interest" will be used to describe all these situations.

Conflicts of interest include a variety of situations in which an employee is faced with conflicting loyalties. Traditionally of most concern are those situations in which regard for a private interest may lead to a disregard of the faculty or staff member’s duties toward the university and its mission. Most often these arise when personal economic interests conflict with the duties toward the institution.

For example, a conflict occurs when a faculty or staff member influences a decision of the university or a decision of a student if a personal economic benefit to the faculty or staff member may arise from that decision. There is a conflict of interest when a purchasing agent buys goods from a company and is an employee of the company at the same time. There is a conflict when a faculty member recommends that goods be purchased from a company in which the faculty member or the faculty member's spouse or child has a financial interest. There is a conflict when a faculty member recommends that a graduate student pursue research in an area that would benefit the commercialization of a product of a company in which the faculty member has a financial interest. There is a conflict when a faculty member directs clinical research involving a medical device for which the faculty receives royalty payments. In these situations the faculty or staff member has the opportunity to use his or her position and influence within the university to advance his or her personal economic gain.

Other conflicts may arise that inhibit the employee's duty of loyalty or commitment to the university. These conflicts, as well as those that represent conflicting time commitments, are sometimes referred to as “conflicts of commitment.” For example, a faculty member enters into a consulting agreement which impairs his or her ability to do research or other activities at the university or which results in the potential transfer of intellectual property rights which would otherwise belong to the university. A faculty member owns a company that competes with the university for corporate and governmental research grants and contracts. In another example, by serving as an expert witness, a faculty member causes his or her own research data and that of university colleagues and students to be revealed prematurely in the course of a lawsuit, thereby compromising the ability of university colleagues and students to publish their research results. There is a conflict when a faculty member accepts a gift of travel expenses from a company manufacturing certain products if one of the faculty member's duties is to do research in order to formulate recommendations on the use of such products which will be transmitted to growers.
through the university's extension service or if one of his or her duties as an extension agent is to give such unbiased recommendations.

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. ¹

Such situations illustrate that certain fundamental principles must be integral to the university's policies concerning conflicts of interest and outside activities and financial interests:

- 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 safety of patients and participants in research must be maintained.

- 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.

These policies must be consistent with the University of Florida Ethics Policy, which provides:

All trustees, officers, and employees of the University of Florida will adhere to the highest ethical and business practices. All actions of the trustees, officers, and employees of the university shall be in compliance with the law, including the Code of Ethics for Public Officers and Employees, Chapter 112, Florida Statutes, and the University of Florida Guidelines, Policies, and Procedures on Outside Activities.

Because a “conflict of interest” depends on the situation in which an individual is placed, rather than the character or actions of the individual, a conflict of interest is not necessarily “bad” or prohibited. Such conflicts confront most of us at various times because we have personal, business, or professional loyalties that may be in conflict. Some conflicts, however, present such a potential for a breach of one's duty to a particular employer, person, or entity that they must either be permitted with conditions, including review and oversight by other institutional

¹Personal relationships may also create conflicting interests. For example, a faculty member has a conflict when he or she has an amorous relationship with a student in his or her class. A business manager has a conflict when he or she supervises an employee who is his or her son or daughter. For guidance in these situations, please refer to the university’s regulation on the employment of relatives (nepotism), Regulation 1.009, and the policy on “Consensual Relationships” in the university’s Policy on Sexual Harassment at http://www.hr.ufl.edu/eeo/sexharassment.htm.
representatives, or prohibited. Generally, if a conflict situation is permitted, specific guidelines and expectations are established prior to permitting the activity or financial interest. The guidelines may allow for periodic review and oversight to minimize the effects of conflicts. Most conflict situations that are of concern and allowable under the law can be handled through disclosure and the setting of appropriate conditions and monitoring requirements.

Each faculty or staff member should recognize that the following types of outside activities, whether compensated or uncompensated, and 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 and responsibilities.

2) Outside activities which use the equipment, personnel, or other resources of the university.

3) Outside activities in which other employees and students supervised and/or evaluated by the employee are also involved.

4) Outside activities (consulting, employment, management, or other contractual relationships) with a person or entity, or financial interests in an entity, that does business with the university, particularly when the faculty or staff member may influence a university decision involving that business.

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 member or when the employee has access to university confidential information of interest to the entity.

6) Outside activities (consulting, employment, management, or other contractual relationship) with, or financial interests in, an entity that is supporting the faculty or staff member's research or educational activities at the university or that will be directly affected by the faculty or staff member’s research or educational activities.

7) Outside activities or financial interests which otherwise interfere with the employee's duties to the institution. These duties include the employee's duties to students and the public clientele served by the faculty or staff member, the duty to maintain the freedom of scholarly inquiry and dissemination of knowledge, and the duty to protect the rights of the university and fellow employees and students to intellectual property developed by them as well as by the faculty or staff member. Only the university through the Vice President for Research or his or her designee may approve any waiver of university rights to intellectual property in connection with an outside activity.

Various activities of faculty members for organizations outside the university may be considered to be within the scope of the faculty member's duties as a university employee. For
example, service for certain professional organizations may be considered within the responsibilities of the faculty member and, if so, would not be an "outside activity" required to be disclosed. However, such activities must be approved as part of the faculty member's university responsibilities, and any use of university resources with regard to these duties must receive appropriate administrative approval. Further, even when these activities are considered within the scope of the faculty member's duties, the faculty member should remain aware of the conflict of interest considerations that may arise when performing work for organizations separate from the university.

In addition, although the reporting requirements concerning outside activities or financial interests do not apply for those periods in which the employee has no appointment with the university unless required under federal grant regulations, the employee should still be aware of the conflict of interest considerations that may arise from such activities. For example, a faculty member employed on a nine-month contract should be aware of the conflicts created by his or her employment during the summer months by the same entity that supports his or her research under a research contract with the university during the remainder of the year. The university must also approve the faculty member's use of university equipment or facilities during any period the employee has no appointment with the university. Only the Vice President for Research or his or her designee can approve the University’s waiver of intellectual property rights in connection with any activities conducted during such periods.

Although not an “outside activity,” an employee who wishes to engage in additional university employment in excess of one full-time equivalent position or who receives compensation as a university employee simultaneously from salaries appropriations and any other appropriation (Other Personnel Services or OPS) must receive approval through the Request for Approval of Additional University Compensation (Appendix B4).

Faculty and staff members are primarily responsible for determining and disclosing their own possible conflicts of interest. Both they and the university benefit from disclosure and discussion of possible problems concerning outside activities and financial interests. Finally, the necessity of disclosing certain outside activities should not obscure the fact that the great majority of the outside activities and financial interests of faculty and staff members are compatible with their university obligations and that the requirements of an outside activities and conflict of interest policy are not meant to discourage the many valuable outside activities of university faculty and staff members.

III. UNIVERSITY OF FLORIDA REGULATIONS AND PROCEDURES

In addition to Florida law applying to all state employees, which is discussed in chapter IV of these Guidelines, the University of Florida has promulgated Regulation 1.011 concerning outside activities and financial interests. The Collective Bargaining Agreement between the University of Florida Board of Trustees (UFBOT) and the United Faculty of Florida (UFF) contains provisions in Article 26 that apply to those faculty and other personnel within the bargaining unit. Other collective bargaining agreements may affect certain classes of university
employees. Regulation 1.011 and Article 26 of the UFBOT/UFF collective bargaining agreement are included as Appendices A1 and A2.

Federal conflict of interest laws and regulations are applicable to some faculty and staff members at the university, including those who work under certain federal grants and contracts, those who conduct clinical trials to be used for Food and Drug Administration applications, and those who are employed by federal agencies. Any University of Florida employee who submits a federal grant or contract proposal or conducts research or educational activities under a federal grant or contract must adhere to the applicable requirements of the funding agency, including those involving the disclosure and regulation of outside activities and financial interests. The specific reporting requirements imposed on persons submitting proposals for Public Health Service and National Science Foundation grants and contracts (and other entities that follow the conflict of interest policies of such agencies) and those carrying out research and educational activities under such grants and contracts are summarized in section B of this chapter.

A. Basic Reporting Requirements

Any university employee engaged in an outside activity or holding a financial interest that must be reported is REQUIRED to complete the University of Florida's Disclosure of Outside Activities and Financial Interests form prior to the commencement of the outside activity or acquiring the financial interest and thereafter at the beginning of each contractual year of employment (generally, the beginning of the fall semester for 9-month appointments and July 1 for all others). If a material change in the information presented occurs during the contract year, a new form must be submitted. Faculty members in the collective bargaining unit are required to use the form found in Appendix B1; all other employees should use the form found in Appendix B2. If more than one activity or financial interest must be reported, separate forms for the various activities and interests must be filled out.

Faculty members (Academic Personnel) are required to indicate annually as part of the effort reporting process whether they have financial interests or are involved in outside activities that must be reported. University Support Personnel System (USPS) and Technical, Executive, Administrative, and Managerial Support (TEAMS) employees are required to indicate on their annual Performance Evaluation forms whether they have such financial interests or outside activities. If the answer is affirmative, the required disclosure forms must have been submitted.

Under the Collective Bargaining Agreement between the University of Florida Board of Trustees and Graduate Assistants United, graduate assistants must disclose in writing “any outside activity which the employee should reasonably conclude may create a conflict of interest.” The Disclosure of Outside Activities and Financial Interests form should be used for this purpose.

The primary purpose of the disclosures required on the Disclosure of Outside Activities and Financial Interests form is to identify those activities and interests that pose potential
conflicts of interest, including conflicts of time commitments. The faculty or staff member makes this initial determination, which should be accomplished in consultation with his or her supervisor. In those situations where a potential conflict of interest exists and the activity or interest is allowable under applicable law, the activity or interest may be allowed after disclosure and review and with the development of appropriate conditions by the faculty or staff member in conjunction with the department chairperson and the college dean or the unit director, or it may be disallowed.

All outside employment, compensated activity, and continuing business activity (including managerial interests or managerial positions) should be reported and approved. Uncompensated activities and financial interests (including financial interests of an employee’s spouse and children) may also need to be reported if they fall within any of the categories described below. In general, an employee must report any compensated outside activity or financial interests which have the potential to create a conflict, including a conflict of time commitments. The reporting requirements apply for any period in which an employee is employed by the university, including any time that the employee is in leave status.

The following outside activities and financial interests must be reported prior to engaging in the activity or acquiring the financial interest:

a) Outside activities in which there is more than an incidental use of university facilities, equipment, and/or services.

b) Outside activities in which a university student or other university employee is directly or indirectly supervised by the employee if the employee in any way supervises or evaluates the student or other employee at the university.

c) Management, employment, consulting, and contractual activities with, or ownership interests in, a business entity (or state agency) which does business with the university. In the case of material financial and managerial interests, the information required extends to the spouse and children of the employee, and for managerial interests, to relatives. For further information on these requirements, please see the discussion in sections 4, 5, and 6 of chapter IV of this document.

d) Management, employment, consulting, and other contractual activities with, or ownership interest in, a business entity which competes with the university.

e) Candidacy for public office.

f) Required use of books, supplies, equipment, or other instructional resources at the University of Florida when they are created or published by the employee, or the employee’s spouse or domestic partner or minor child(ren) or by an entity in which the employee, or the employee’s spouse or domestic partner or minor child(ren) have a financial interest, if more than $500 is received or expected to be received annually by any or all of them in the aggregate.
g) Professional compensated activities, including, but not limited to, consulting, teaching at another institution, participating in an activity in which an honorarium is to be received, and employment as an expert witness.

h) Service on a board of directors or board of trustees, service as an officer or other management interest or position in an entity.

i) Any outside compensated employment.

j) Any employment, contractual relationship, or financial interests of the employee which may create a continuing or recurring conflict between the employee's interests and the performance of the employee's public responsibilities and obligations, including time commitments. This includes any outside activity in which the employee is required to waive rights to intellectual property and any outside activity or financial interest with a business entity which supports the employee’s research or training program at the university.

k) Outside activities and financial interests required to be reported under federal contract and grant regulations.

Faculty members in the collective bargaining may not need to report certain activities and financial interests or certain activities and interests. Please refer to Article 26 of the UFBOT/UFF collective bargaining agreement (Appendix A2) for applicable reporting requirements.

In making the required disclosure on the Disclosure of Outside Activities and Financial Interests form, the following information must be furnished:

a) Name of employing or contracting entity or person, or name of entity in which the financial interest is held, and nature of its business.

b) Involvement of students and other employees in the activity, employing entity, or entity in which the financial interest is held, if that involvement is known to the employee making the disclosure.

c) Nature of activity or financial interest (description of equity interest or intellectual property), including time spent if an activity is involved (estimated hours per week including travel time). The source and type of compensation must be noted, and in the case of legal representation or service as an expert witness, all parties to the matter must be identified.

d) Location and anticipated dates of activity.

e) Any conditions of the activity which involve waiving or impairing the employee's or university's rights to intellectual property.
f) Use of university equipment, facilities, or services in connection with the activity.

g) Number of other outside activities and financial interests previously filed for the contractual year.

h) Whether the activity or financial interest was reported in the previous contractual year.

Other information may also be requested in order to assure a complete review of the activity.

The responsibility for adhering to the law and regulations on conflict of interest and outside activities rests with the individual faculty or staff member. Full disclosure and discussion of all potential and actual conflicts make possible the addressing of the issues involved and prevent problems arising for both the faculty or staff member and the university in the future. The review and oversight responsibility rests with the department chairperson and the dean or director of the college or other unit in which the faculty or staff member is employed. An employee must provide sufficient information to those with the review and oversight responsibility to enable them to make an informed decision concerning the allowance of the outside activity or financial interest.

Any employee engaging in outside activities must recognize that he or she is performing such activities as an individual and may not represent that he or she is acting on behalf of the university. For example, an employee may not use University of Florida letterhead or a University of Florida email address in conducting outside activities. The employee must take reasonable precautions to insure that the outside employer or other recipient of services understands that the employee is engaging in the outside activity as a private citizen and not as an employee, agent, or spokesperson of the university.

B. 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 other financial interests of persons involved in sponsored research projects funded by the Public Health Service (PHS) 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.

Any “Investigator” submitting or working on projects funded by the PHS or the NSF must abide by these requirements. An Investigator is defined as the principal investigator, co-principal investigator, project director or any other personnel, regardless of title or position, whether or not employed by the university, responsible for the design, conduct, or reporting of the proposed or funded research or educational activities. For the purpose of determining a “Significant Financial Interest,” as defined below, an “Investigator” also includes such a person’s spouse and dependent children.
Any personnel submitting a grant or contract proposal to the National Science Foundation through the university or conducting research or educational activities pursuant to such a federal grant or contract at the university as an Investigator must disclose any “Significant Financial Interest” that would reasonably appear to be affected by the proposed or funded research activities, including interests maintained in entities that would be so affected. A “Significant Financial Interest” under NSF regulations refers to: salary or other payments for services, such as consulting fees and honoraria; equity interests, such as stocks and stock options; and intellectual property rights, such as patents, copyrights, and royalties. A Significant Financial Interest for NSF does not refer to salary or other remuneration from the university; income derived from seminars, lectures or teaching engagements sponsored by public or nonprofit entities; income derived from service on advisory committees or review panels for public or nonprofit entities; or salary, royalties or other payments that, when aggregated for the Investigator and his or her spouse and dependent children, are not expected to exceed $10,000 over the next 12 months. An equity interest that, when aggregated for the Investigator, spouse, and dependent children, does not exceed $10,000 and does not represent more than a five percent ownership interest in any entity is also not considered a Significant Financial Interest.

Any personnel submitting a grant or contract proposal to the PHS through the university or conducting research or educational activities pursuant to such a federal grant or contract as an Investigator must disclose any “Significant Financial Interest” that would reasonably appear to be related to the Investigator’s institutional responsibilities. A Significant Financial Interest for PHS with regard to any publicly traded entity exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure and the value of any equity interest when aggregated exceeds $5,000. Remuneration includes salary and any payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorship, travel reimbursement); equity interest includes any stock, stock option, or other ownership interest, as determined by public prices or other reasonable measures of fair market value. 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 twelve months preceding the disclosure exceeds $5,000, or the Investigator holds any equity interest. The term Significant Financial Interest does not include the following types of financial interests: salary, royalties, or other remuneration paid by the university to an Investigator who is currently employed; income from seminars, lectures, or teaching engagements sponsored by a federal, state, or local government agency, or an institution of higher education as defined at 20 U.S.C. 1001(a); or income from service on advisory committees or review panels for a federal, state, or local government agency, or an institution of higher education. Investigators must also disclose any reimbursed or sponsored travel regardless of the dollar amount.

Significant Financial Interests must be disclosed at the time of the submission of the proposal, but approval of the outside activities and financial interests (with conditions if warranted) need not occur until the project has been funded. All Investigators on NSF and PHS proposals must fill out and sign a Division of Sponsored Programs Disclosure of Financial Interest form before the proposal is submitted by the Division of Sponsored Programs to these agencies (Appendix B5a for PHS; Appendix B5b for NSF). If a "Significant Financial Interest" is disclosed, the employee must attach a copy of his or her Disclosure of Outside Activities and
Financial Interests form disclosing the interest. The Disclosure of Financial Interest form (with the Disclosure of Outside Activities and Financial Interests form if needed) must be part of the package submitted for review and approval through the usual departmental, college, and unit approval process using the DSR-1 form. It is the principal investigator’s responsibility to ensure that Division of Sponsored Programs Disclosure of Financial Interest forms are obtained from all Investigators in order to meet proposal application deadlines. The Division of Sponsored Programs requires at least three business days to review proposals.

If there is no Significant Financial Interest at the time of submission of the proposal, but such an interest develops at any point prior to funding, it must be reported and approved prior to the time the project is funded. The federal regulations also require that the disclosures be made annually during the course of the research, which is consistent with the university’s requirement that outside activities and financial interests be disclosed at the beginning of each academic year. The employee must file a new disclosure within 30 days if a new Significant Financial Interest is obtained, which is consistent with the university’s requirement that any material changes to outside activities and financial interests must be reported during the academic year. Review and approval or disapproval of the interests disclosed during the course of a research project must be accomplished within 60 days.

The dean or director (or designee) and the institutional official (or designee) are responsible for reviewing each disclosure to determine if there is a financial conflict of interest. The University, through the department chairperson or supervisor (or designee) and dean or director (or designee) and the Division of Sponsored Programs through the Office of Research Compliance, is required to manage, reduce or eliminate the conflict. Conditions that might be imposed in such cases include public disclosure of the conflict, disclosure of the conflict to participants in projects involving human subjects, modification of the research design, restricting an Investigator from participating in parts of the research, or monitoring of the research by independent reviewers. (Please see the sample Conflict of Interest Monitoring Plan at Appendix B8.) If adequate measures are not feasible, the Investigator may have to discontinue the compensated activities, divest himself or herself of the financial interest, or terminate the research. The Investigator must abide by the conditions under which the research is permitted.

Prior to expenditure of any funds under a PHS project the university will submit a conflict of interest report to the PHS awarding component and ensure that an appropriate management plan concerning the conflict has been implemented. A report will be submitted within 60 days for new or newly identified financial conflicts. For any conflict previously reported by the university with regard to an ongoing PHS project, the university will submit an annual report that addresses the status of the conflict and any changes to the management plan.

Pursuant to the PHS regulations, if a conflict is not identified, including failure by an Investigator to disclose a Significant Financial Interest which is determined to be a conflict, or if an Investigator fails to comply with a conflict management plan, then the university will review the research to determine whether any bias in the design, conduct or reporting of the research exists. If necessary, the university will update the conflict report it previously submitted to the PHS awarding component and if bias is found will submit a mitigation report.
Where the PHS funded research involves a subrecipient, the subrecipient will follow the financial conflict of interest policy of the subrecipient. The subcontract shall provide that the subrecipient shall report identified financial conflicts for its Investigators to the university to allow the university to report to the PHS awarding component.

University will post information concerning identified financial conflicts with regard to PHS-funded research on a public website housed on the Office of Research web page.

For further information with regard to federal contract and grant requirements, please contact the Division of Research Compliance at 294-1632.2

C. Guidelines for Allowance of Outside Activities and Financial Interests

The university recognizes that there are conflict situations which must be prohibited, conflict situations which may be allowed with conditions and oversight, and outside activities and interests that are generally allowed. The guidelines that follow are designed to assist faculty, administrative and professional staff, and other employees, as well as department chairpersons, directors, deans, and other supervisors, in evaluating conflict of interest situations.

1) Prohibited outside activities and financial interests:

Any outside activities or financial interests which are prohibited by state law cannot be allowed. The most significant of these prohibitions for faculty members are those concerning financial interests, employment, and other contractual relationships with an entity doing business with the university. This prohibition is explained in the following section

2 A Note on FDA Requirements for Clinical Trials. Under Food and Drug Administration (FDA) regulations, if sponsors of clinical trials are to use the results in support of marketing applications, they must obtain certain financial information from clinical investigators. This information includes:

(a) Financial arrangements under which the value of the compensation could be influenced by the outcome of the study. (It should be noted that such personal income would be prohibited under Florida’s Code of Ethics for Public Employees; please refer to section IV (5) of these Guidelines.)

(b) Payments to the university or the investigator of a value greater than $25,000 (other than for purposes of conducting clinical trials) during the time the clinical investigator is carrying out the study and for one year following the completion of the study. For example, a grant to fund ongoing research, or compensation in the form of equipment or retainers for ongoing consultation or honoraria, would meet this requirement. (Such funds paid to the investigator personally would be prohibited under Florida’s Code of Ethics for Public Employees unless an exemption applied.)

(c) A financial interest in the products which are the subject matter of the clinical trial (such as, a patent or income from a licensing agreement).

(d) A “significant financial interest” in the sponsor of the study. “Significant financial interest” means any financial interests in a nonpublicly-traded company of any amount or any equity interest in a publicly trade company that exceeds $50,000. (Generally, such interests would be precluded without an exemption under Florida’s Code of Ethics.)

Financial interests include those of the investigator’s spouse and minor children. Of course, any disclosure of financial interests in conjunction with a clinical trial should be consistent with the employee’s Disclosure of Outside Activities and Financial Interest.
discussing Florida law and generally would prohibit, for example, any transaction between the university and a company owned by a faculty member unless one of the exemptions set forth in the law applies. Similarly, a research contract between the university and a company cannot support the research of a faculty member who has a contractual relationship (such as a consulting arrangement) with or a financial interest in that company unless an exemption applies.

Also prohibited under Florida law are those outside employment or contractual relationships which would create a "continuing or frequently recurring conflict" between the employee's private interest and the performance of his or her public duties or "that would impede the full and faithful discharge of his or her public duties." Thus, an employee employed to develop software in a given field for the university could not be employed to develop the same kind of software elsewhere. Such employment would create a "continuing or frequently recurring conflict." Further, a University of Florida employee could not hold an employment or consulting arrangement involving litigation against the university or the Florida Board of Governors because such would impede the faithful performance of his or her duties toward the university. Outside activities or contractual relationships with a company that supports the research or training activities of a faculty member create such a conflict and, thus, are not allowed unless an exemption applies.

2) Outside activities and financial interests that may be permitted only after review and with appropriate conditions if necessary:

Among such activities and financial interests are the following:

a) Outside activities or financial interests allowed under an exemption to state law. With regard to doing business with the university, for example, this includes the exemption for research and license agreements or transactions of under $500 in a calendar year. The exemption for research and license agreements requires special approvals as explained in section IV(6)(e). The procedures concerning proposed business transactions with the university are discussed below in section IV(5).

b) Outside activities or financial interests in a company that will be directly and significantly affected by the research activities of the faculty or staff member. Such activities or financial interests can only be permitted if they do not create a “continuing or recurring conflict,” as noted above.

c) Outside activities or financial interests in a company conducting educational or research activities which could be conducted at the university.

d) Outside activities or financial interests in a company involving students or employees of the university in any way evaluated,
taught, or directed by the faculty or staff member at the university. Such situations involving students or employees are strongly discouraged and should be avoided.

e) Outside activities which involve more than an incidental use of university facilities, equipment, and services. The use of any university personnel should be disallowed unless the services provided are generally available to the public.

f) Outside activities or financial interests related to the use of instructional materials as more fully explained below.

Such outside activities and financial interests may be allowed and such allowance may require that conditions have been established through which any conflicts may be minimized. For example, a conflict situation may be allowed under a written agreement with the faculty member which requires oversight in some instances by persons external to the faculty member's department or college. In addition, disclosure of a conflict situation to others besides those reviewing the Disclosure of Outside Activities and Financial Interests may be required. Disclosure of financial interests (including royalties from inventions) may need to be made in research protocols and consent forms to be executed by human subjects and/or patients. Such a disclosure may also be required in a publication resulting from the research.

As to instructional materials, employees who are instructors are responsible for the assignment of such materials for their students. The selection of these materials must be based on academic reasons and not on financial gain for the individual employee, the employee’s spouse or domestic partner or minor child(ren) or the University of Florida. These persons may not receive any financial benefit from materials reflecting general course information or assignments or evaluation materials (such as examinations, quizzes, syllabi and extra credit assignments) used in university courses or other university instructional activities. At the same time, an employee, the employee’s spouse or domestic children or minor child(ren) may benefit from the sale or use of required books, supplies or other resources used in University of Florida courses or other university instructional activities if the following conditions are followed: (i) the department chair and dean or director have approved the arrangement on the Disclosure of Outside Activities and Financial Interests form, and (ii) the materials have been selected for academic reasons independent of any financial gain for the persons involved, are offered at a fair market price, have been adopted for use at other higher education institutions, are the original works or creations of the employee and not a collection of the works of others, are protected by copyright, patent, or trademark, and are published or produced by an incorporated or registered publisher, company, or entity. Their use must not require the user to waive any intellectual property rights.

Finally, recognizing that colleges and departments within the university have unique attributes, a unit may develop guidelines under college auspices that will assist members of its faculty and staff to deal with the particular conflict situations that may arise with regard to their particular services and fields. For example, the guidelines for employees in the Institute for Food
and Agricultural Sciences are found in UF Regulation 6.015. (Appendix A3; supplemental form, Appendix B3). All such guidelines must be approved by the dean or director of the unit involved and be on file in the offices of the dean, the General Counsel, Research Compliance and the Provost.

3) **Outside activities and financial interests that are generally allowed:**

In general, most other outside activities are allowed if they do not interfere with the employee's performance of his or her university obligations. However, determining whether a particular situation involves a conflict of interest is dependent on reviewing all the facts of the specific situation, which underscores the importance of the disclosure and discussion of possible conflicts.

### D. Review Procedures and Sanctions

The following persons must review and approve the activities and financial interests reported on the Disclosure of Outside Activities and Financial Interests form: (1) chairperson, (2) dean or director, (3) Office of Research, if intellectual property rights are to be waived, and (4) Purchasing Services (or other contractual authority), if applicable.

If there are any questions or concerns with regard to a particular disclosure, a conference is encouraged between the faculty or staff member and his or her chairperson or other immediate supervisor.

An employee’s failure to report outside activities and financial interests under university regulations or Article 26 of the UFBOT/UFF collective bargaining agreement, an employee’s engaging in the activities or holding the financial interests without the university’s approval, and an employee’s failing to follow any conditions imposed pursuant to the university’s approval of such activities are grounds for disciplinary action. Examples of sanctions are: disallowance or limiting outside activities, changes in assignment, limitations on research activities, fines, reduction in pay, demotion, written reprimand, suspension without pay, and termination for cause. The employee may be required to turn over to the university all or part of the compensation from an unapproved outside activity. If an activity or interest has not been properly disclosed, the employee may be required to disclose the activity or interest in all subsequent presentations of research results. Finally, as noted in the following section, a violation of the State’s Code of Ethics may be grounds for various penalties imposed under state law.

### E. Other University of Florida Conflict of Interest Policies

The College of Medicine has promulgated a Policy on Pharmaceutical, Medical Device, and Biotechnology Industry Conflicts of Interest, University of Florida Regulation 5.0764 (Appendix A4). This policy applies to all employees and appointees (“College of Medicine personnel” under the regulation) of the College of Medicine. The policy covers activities and gifts not necessarily covered by UF Regulation 1.011, state law, or federal requirements, and the
requirements of the policy are supplemental to these requirements. The purpose of the policy is
to increase transparency respecting interactions between College of Medicine personnel and the
pharmaceutical, medical device, biotechnology, hospital and research equipment supply
industries (and their representatives) and to eliminate or mitigate conflicts of interest created by
these interactions. The detailed policy is available at http://coi.med.ufl.edu/policies/uf-policies/.

Direct support organizations and other affiliated organizations of the university, such as
the University of Florida Foundation, Inc., the University Athletic Association, Inc., the
University of Florida Research Foundation, Inc., and the Florida 4-H Foundation, Inc., have
conflict of interest policies applicable to their directors, officers, and employees. University
employees acting as directors or officers or providing services to the organization must disclose
any financial interests in any business entity doing business with the direct support organization
and must comply with the reporting and other requirements of the organization’s conflict of
interest policy.

The University of Florida Research Foundation, Inc. (UFRF) may license technologies to
commercial enterprises and may take ownership interests in commercial enterprises that license
university technology and/or support ongoing research at the university. In such cases, the
potential conflicts of the faculty members and other employees involved with the commercial
enterprise are handled through the process set forth in section IV(6)(e) of this document. In
addition, the University of Florida and UFRF have adopted a "University of Florida-University of
Florida Research Foundation, Inc. (UFRF) Institutional Conflict of Interest Policy" to further
limit personal conflicts and to mitigate institutional conflicts. The policy is found at Appendix
A5.

F. Use of University Equipment, Facilities, and Services

Any use of university equipment, facilities or services with regard to an outside activity
must be approved prior to the activity. In general, the use of these resources will be allowed only
on a noninterference basis, and a charge may be assessed. The form for this purpose is the
Request to Use University Equipment, Facilities, and Services, a copy of which is found at
Appendix B6.

IV. CODE OF ETHICS FOR STATE OF FLORIDA EMPLOYEES

In formulating the Code of Ethics for employees and officials of the State of Florida, the
Florida Legislature stated that it "is essential to the proper conduct and operation of government
that public officials be independent and impartial and that public office not be used for private
gain other than the remuneration provided by law." At the same time the Legislature recognized
that public officials and state employees should not be "denied the opportunity, available to all
other citizens, to acquire and retain private economic interests except when conflicts with the
responsibility of such officials to the public cannot be avoided." The Code of Ethics for Public
Officers and Employees is designed, therefore, to "protect against any conflict of interest and
establish standards for the conduct of elected officials and government employees in situations
where conflicts may exist."
The Code of Ethics for Public Officers and Employees is set forth in Part III of Chapter 112, Florida Statutes. The Code of Ethics provides standards of conduct for state employees, post-employment restrictions for certain employees, requirements concerning disclosure of financial interests for certain employees, a description of the role of the Florida Commission on Ethics, and penalties and procedures with regard to violations of the standards of conduct. On an annual basis, the Florida Commission on Ethics publishes a brochure entitled "Guide to the Sunshine Amendment and Code of Ethics for Public Officers and Employees" that outlines the major provisions of the Code. Further information may be found on the Commission's website at www.ethics.state.fl.us.

The penalties that may be imposed against a state employee for infractions of the Code of Ethics include dismissal from employment, suspension without pay, demotion, reduction in salary, forfeiture of a portion of salary, a civil penalty, restitution of benefits received because of the violation, and public censure and reprimand.

The following list of issues highlights various provisions of the Code of particular importance to members of the University of Florida community. It should not be considered as encompassing all applicable laws or as a substitute for reading the wording of the actual laws.

1) **Misuse of position**

The Code of Ethics prohibits any state employee's corrupt use (or attempted use) of his or her official position to secure a special benefit or exemption for the employee or others.

2) **Use of Information**

A state employee is not permitted to disclose or use information not available to the general public and "gained by reason of his or her official position" for the employee's "personal gain or benefit or for the personal gain or benefit of any other person or business entity."

For example, this provision is critical in evaluating conflicts that might arise in outside consulting arrangements of faculty members. In such consulting, the faculty member may not disclose unpublished research results or university technology not previously made available to the general public to the outside firm.

3) **Gifts and honoraria**

A state employee is prohibited from soliciting or accepting gifts, loans, or anything of value based upon the understanding that the employee's official action(s) or judgment would be influenced by such a gift. Further, an employee or an employee's spouse or minor child(ren) may not accept "any compensation, payment, or thing of value" when such employee knows, "or with the exercise of reasonable care, should know," that it is given to influence official actions of the employee.
Under the university’s Standard of Conduct Regarding Purchases: “It shall be a breach of ethical standards for any employee of the university to accept, solicit, or agree to accept a gratuity of any kind, form or type in connection with any contract for commodities or services.”

Certain state employees called "reporting individuals" (or "specified state employees") and "procurement employees," including many who deal with decisions involving the purchase of goods or services, are restricted by law from soliciting and accepting any gifts, as well as honoraria, from certain individuals or entities. A discussion of these restrictions is found in Appendix C of these Guidelines.

Finally, College of Medicine personnel should consult University of Florida Regulation 5.0764 on Pharmaceutical, Medical Device, and Biotechnology Conflicts of Interest for restrictions with regard to gifts from the pharmaceutical, medical device and biotechnology industries. (See Appendix A4.)

4) **Doing business with the university, Sections 112.313(3) and 112.3185, Florida Statutes**

A state employee acting as a purchasing agent for a state agency, such as the University of Florida, is prohibited from directly or indirectly purchasing, renting, or leasing any real property, goods, or services for the agency from any business entity of which the employee or his or her spouse or child(ren) is an officer, partner, director, or proprietor. If an employee is delegated the responsibility of purchasing realty, goods, or services for the university, the employee is also prohibited from entering into such a transaction with a business entity of which the employee or his or her spouse or child(ren) or any combination of them has a material interest. A "business entity" is defined in the law as "any corporation, partnership, limited partnership, proprietorship, firm, enterprise, franchise, association, self-employed individual, or trust, whether fictitiously named or not, doing business in this state." "Material interest" is defined as "direct or indirect ownership of more than 5 percent of the total assets or capital stock of any business entity." It should be noted that any University of Florida employee authorized to make purchases with a UF Purchasing Card would be considered a purchasing agent and bound by the restrictions set forth in this paragraph.

Any employee acting in a private capacity may not rent, lease, or sell any realty, goods, or services to the university. An employee is acting in a private capacity if he or she owns a material interest in a business entity from which the university rents, leases, or sells realty, goods, or services, if the employee is an officer or director of a corporation selling or leasing to the university, or if he or she acts as an agent of the business to facilitate a sale or lease to the university. The prohibition does not apply when the employee is not in a position at the university which allows him or her to in any way influence the lease or purchase or regulate the services provided.

It should be noted that the provisions of Section 112.313(3) do not affect or prohibit any contracts that were entered into prior to an employee's employment by the university. Further, as noted below under paragraph (6), the law provides exemptions from these requirements in certain
cases. If an employee discloses a material financial interest or managerial interest which is allowed as to a particular purchase or contractual arrangement, the employee is responsible for insuring that a copy of the approved Disclosure of Outside Activities and Financial Interests is provided to Purchasing Services or to the university unit that is entering into the business arrangement.

Section 112.3185, Florida Statutes, applies to the procurement of contractual services. It prohibits an employee "who participates through decision, approval, disapproval, recommendation, preparation of any part of a purchase request, influencing the content of any specification or procurement standard, rendering of advice, investigation, or auditing or in any other advisory capacity in the procurement of contractual services" from becoming an employee of a person or entity contracting with the university for the provision of these services. This statute also prohibits a university employee "acting in his or her official capacity" from directly or indirectly procuring contractual services for the university from "any business entity of which a relative\(^3\) is an officer, partner, director, or proprietor or in which such officer or employee or his spouse or child, or any combination of them, has a material interest." The law provides no exemptions from the prohibitions of this statute.

5) **Conflicting employment and contractual relationships, Section 112.313(7), Florida Statutes**

A faculty or staff member of the university may not be employed by or have a contractual relationship with a business entity or a state agency which is "doing business" with the university. For example, if a business entity sells services or products to the university, it is doing business with the university. This may preclude a university employee who deals with such procurement from having a contractual relationship with the company. If the entity enters into a research agreement with the university, it is "doing business" with the university. This would preclude a principal investigator from having a contractual arrangement (such as, a consulting agreement) with the company that also sponsors his university research under a contract with the university. An exemption for such an agreement may be allowed as set forth in section IV(6)(e) below.

If the university receives a gift (not a contract) from a private entity, that entity would not be "doing business" with the university. If the employee provides uncompensated volunteer services to a not-for-profit entity, that is not considered an "employment or contractual relationship" with that entity. However, it should be noted that the activity may still present a conflict and may need to be disclosed under other provisions of the law or university regulations.

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\(^3\) "Relative" is defined in the law as anyone related to an employee as “father, mother, son, daughter, brother, sister, uncle, aunt, first cousin, nephew, niece, husband, wife, father-in-law, mother-in-law, son-in-law, daughter-in-law, brother-in-law, sister-in-law, stepfather, stepmother, stepson, stepdaughter, stepbrother, stepsister, half brother, half sister, grandparent, great grandparent, step grandchild, step great grandchild, person who is engaged to be married to the employee” or who otherwise holds himself or herself out as or is generally known as the person whom the employee intends to marry or with whom the . . . employee intends to form a household,” or any other person having the same legal residence as the employee.
If an employee (or an employee’s spouse, domestic partner or other relative) has a material financial interest or a managerial interest in an entity, or the employee has an employment or other contractual relationship with an entity, that proposes to do business with the university and the employee is involved in the procurement or contractual process for the entity or for the university (including but not limited to making recommendations), the employee must inform the university office making the procurement or entering into the contract of his or her financial interest prior to the procurement or the signing of the contract. A determination may then be made whether the procurement and/or contract is allowable under Florida law as well as university regulations. An approved copy of the Disclosure of Outside Activities and Financial Interests form must be filed with university’s Purchasing Services division (with the purchase requisition if a purchase requisition is required) or the contracting authority at the university prior to the purchase being made or the university’s entering into a contract with the entity.

6) Exemptions from Section 112.313(3) and (7)

A transaction otherwise precluded under the prohibition against doing business with one's agency (Section 112.313(3), Florida Statutes) or the prohibition on conflicting employment and contractual relationships (Section 112.313(7), Florida Statutes) may be allowed under one or more of various exemptions provided in the law. The most commonly applied exemptions in the state university setting are:

a) Competitive bid with disclosure to the Florida Department of State

If the contract involved is awarded under competitive bids and the employee or his or her spouse or child has not participated in formulating the bid specifications or determining the lowest or best bidders, and the employee or his or her spouse or child has not used or attempted to use his or her influence to persuade the university to enter into such a contract, the contract may be entered into. Prior to the submission of the bid, the employee must file a statement with the Florida Department of State disclosing his or her interest and/or that of his or her spouse or child and the nature of the intended contract.

b) Certain goods and services; emergency purchases

Other exemptions are made for legal advertising in a newspaper, utilities services, and passage on a common carrier (bus, airplane, train, or the like). An employee may also purchase goods or services "at a price and upon terms available to similarly situated members of the general public, from a business entity which is doing business with his or her agency." Also exempted are emergency purchases or contracts which must be made in order "to protect the health, safety, or welfare of the citizens of the state."

c) Transactions of less than $500 in a calendar year

An exemption is also made if the "total amount of the transactions in the aggregate between the business entity and the agency does not exceed $500 per calendar year."
d) Research, license and related agreements

An exemption is provided which allows a faculty (or staff) member to be a consultant or be otherwise employed by a company or have an ownership interest in a company that is licensing the faculty member's technology from the university. The exemption also allows a faculty member with an employment or contractual relationship with a business entity or an ownership interest in a business entity to be involved in work on a research contract between the university and the business entity. However, such relationships are allowed only with the prior review of the faculty or staff member's department and college and approval by the applicable Senior Vice President with the final approval by the chair of the University of Florida Board of Trustees or the chair’s designee.

This exemption was passed to facilitate transfer of university-developed technology to commercial enterprises by making possible license agreements and research contracts with business entities with which the faculty member-inventors have employment or other contractual relationships. Technology transfer is an important ancillary result of the university's research and educational efforts. To assure that the primary mission of the university is not compromised, however, an employee's outside activities with regard to transfer of the university's technology or university research must be disclosed and approved.

The procedures for requesting the research and license exemption are set forth in Appendix B7 (Request for Exemption under Section 112.313(12)(h), Fla. Stat.) of these Guidelines. In granting the request, the university's interests in protecting the educational progress of students, the integrity of research, the dissemination of research results, the appropriate evaluation of employees, and the use of university equipment and personnel will be examined closely. In general, the faculty or staff member will be granted the exemption only with his or her agreement to follow certain conditions which allow for appropriate oversight. Please refer to Appendix B8 for a monitoring plan template that is used to assist in the formulation of these conditions. If the exemption is approved, the faculty or staff member's department and college must make significant commitments to the oversight process.

7) Disclosure of Financial Interests and Post-Employment Restrictions, Sections 112.3145, 112.313(9), and 112.3185, Florida Statutes

Certain state officers and public employees ("reporting individuals") are required to disclose certain financial interests on an annual basis. Reporting individuals include: the university's president and vice presidents, legal counsel, business managers, purchasing agents (persons with signatory authority for contracts) having the power to make any purchase exceeding the Category One threshold amount (currently $20,000), finance and accounting directors, personnel officers, and deans. A list of "reporting individuals" is provided by the university to the Commission on Ethics on an annual basis. Prior to June 1 of each year, these persons are mailed a copy of Form 1, which indicates the required financial disclosures. The form must be filed with the Commission on Ethics by July 1. New employees in these positions must file within thirty days from the date of appointment. Upon leaving employment a Form 1F must be filed. A fine is imposed if the form is not filed in a timely manner.
Reporting individuals must also abide by restrictions on gifts, honoraria, and lobbyist “expenditures.” Other employees involved in the procurement process (“procurement employees”) are also restricted in their receipt of gifts and honoraria. Please refer to Appendix C.

Certain university employees are prohibited from personally representing another person or entity for compensation before the university for a period of two years after leaving their positions (unless employed by another state agency). Employees bound by this restriction include the president, vice presidents, and deans.

Any former employee is barred from having an employment or other contractual relationship with any business entity in connection with a contract in which the employee participated personally and substantially by recommendation or decision when he or she was a university employee. A former employee is also prohibited from having any employment or contractual relationship for two years with any business entity in connection with a contract for services which was within his or her responsibility while serving as a university employee.

V. CONCLUSION

The outside activities of University of Florida faculty and staff members are often of great value to the community as a whole and further the mission of the university. They also may serve important personal interests. These activities are of concern to the university when they interfere with the faculty member or staff member's obligations to the university. Indeed, all members of the University of Florida community must be concerned that the university's mission not be compromised through the outside activities and interests of its faculty and staff members. Thus, the university's policies and procedures are designed to encourage allowed activities while providing for the disclosure, review, and oversight, if needed, of activities in which conflicts might occur. The primary responsibility for compliance and for furtherance of these goals rests with the individual faculty or staff member.