

Welcome to USF Health at the University of South Florida, Tampa

The logo for USF Health, featuring a small icon of a person and the text "USF Health" in blue.

Menu

- [News](#)
- [Education](#)
- [Research](#)
- [Patient Care](#)

- [USF Health](#)
- [USF](#)
- [Search](#)

- [USF Health](#)
- [Faculty Affairs](#)
- [Conflict of Interest](#)

- [Faculty Affairs Home](#)
- [Appointment & Recruitment](#)
 - [Appointment & Recruitment Process](#)
 - [Courtesy Appointment](#)
 - [Joint Appointment](#)
 - [Licensing & Privileging](#)
 - [Relocation Information](#)
 - [Voluntary Appt](#)
- [Compensation](#)

USF

- [Explanatory Memorandum from Provosts Office](#)
- [Faculty Extra Compensation Form](#)
- [Policy Statement](#)
- [Procedures](#)

Research

- [Research Incentive Program](#)

USF Health

- [Faculty Salary Adjustments](#)

MCOM

- [AAMC Faculty Salary Tables/Asset Investment Management Systems \(AIMS\)](#)
- [Clinical Faculty Compensation](#)
- [Clinical Research Support Salary](#)
- [Education/Contract Support Salary](#)
- [Performance Based Research Faculty Salary Enhancement Policy](#)
- [Salary Adjustment Guidelines for PhD and Non-Clinically Predicating MD Faculty \(MCOM\)](#)
- [Promotions & Tenure](#)
 - [Governance](#)
 - [Medicine](#)
 - [Nursing](#)
 - [Pharmacy](#)
 - [Public Health](#)
 - [USF Tenure Guidelines](#)
- [Development](#)
 - [Continuing Professional Development](#)
 - [Military Leave](#)
 - [New Faculty Orientation](#)
 - [Professional Development Leave](#)
 - [REACH](#)
 - [Sabbatical Leave \(Tenured\)](#)
 - [Sabbatical Leave \(MCOM Non-Tenured\)](#)
- [Separations](#)

Departing Faculty Information

- [Accrued Leave Payouts](#)
- [Exit Information](#)

Voluntary

- [Retirement](#)
- [Separations](#)

Involuntary

- [Dismissals for Cause/Disciplinary](#)
- [Grievances](#)
- [Layoffs](#)
- [Non-Reappointment](#)
- [Resources](#)
 - [Assignment & Evaluation](#)
 - [Awards](#)

- [Conflict of Interest](#)
 - [Faculty Council](#)
 - [Faculty Disclosure Portal](#)
 - [Forms](#)
 - [General Counsel](#)
 - [Human Resource Benefits](#)
 - [Links & Resources](#)
 - [Policies, Procedures and Guidelines](#)
 - [Research](#)
 - [USF Health Deans & Chairs List](#)
 - [USF Web Applications](#)
 - [Contact Us](#)
-

Conflict of Interest

Effective March 17, 2003

Forms

[ROAD](#) - Electronic submission of USF Health Report of Outside Activity Form and USF Use of Equipment, Facilities and Services Form

Summary

Presents and discusses circumstances which can create real or perceived conflicts of commitment and conflicts of interest. Defines key terms. Details substantive prohibitions and restrictions. Describes the procedures for disclosing financial and other interests, reviewing disclosures, reporting information to other agencies, implementing the policy, appealing decisions concerning the policy, and sanctioning non-compliance with the policy. Establishes requirements for ongoing certifications and financial disclosures. Specifies special restrictions on human subjects research.

Purpose and Scope of Policy

This policy relates to conflicts of interest and conflicts of commitment and applies to all USF Health officers, faculty, staff, students and committee members involved in the academic, clerical or managerial mission of the University ("Health-Affiliated Individuals"). The purpose of this policy is to assist Health-Affiliated Individuals in avoiding both actual and apparent conflicts of commitment or interest between his or her University obligations and his or her private interests. **Every Health-Affiliated Individual has an obligation to become familiar with, and abide by, the provisions of this policy.**

Conflicts of interest are common and practically unavoidable in a modern research university. However, Health-Affiliated Individuals should conduct their affairs so as to avoid or minimize conflicts of commitment or interest, and must respond appropriately when conflicts of commitment or interest arise. The purposes of this policy are to encourage the multiple and diverse interests of Health-Affiliated Individuals while protecting the University's integrity, mission, patients, students and resources. To this end, the objectives of this policy are to educate Health-Affiliated Individuals about situations that generate conflicts of interest, to provide means for the Health-Affiliated Individual and the University to manage conflicts of interest, to promote the best interests of students and others whose work depends on faculty direction, and to describe situations that are prohibited.

Institutions and Health-Affiliated Individuals bear a shared responsibility for the oversight of financial interests in research, yet each remains accountable for the effectiveness of the oversight system.

In addition, federal regulations require institutions to have policies and procedures that ensure that Investigators disclose any significant financial interests that may present an actual or potential conflict of interest in relationship to sponsored research projects. Such disclosure must be made prior to the submission of a proposal for funding or at the time a potential conflict develops.

It is the responsibility of each Health-Affiliated Individual to report identified conflicts of interest, regardless of the magnitude, appropriateness, time or location of the activity. All financial interests must be reported, whether or not the financial interest reaches the "significant financial interest" threshold defined in this policy, or any other threshold established by state or federal law.

General Principals

Preamble

Individual Conflicts of Interest

Competing interests, particularly those engendered by a desire to advance scientific knowledge or to achieve professional recognition, are an inescapable fact of academic life. Most are managed through institutional policies and practices, and through the constraints imposed by the scientific method. Yet financial interests in human subjects research are distinct from other interests inherent in academic life that might impart bias or induce improper behavior, because financial interests are discretionary, and because the perception is widespread that they may entail special risks. Specifically, opportunities to profit from research may affect - or appear to affect - a researcher's judgments about which subjects to enroll, the clinical care provided to subjects, even the proper use of subjects' confidential health information. Financial interests also threaten scientific integrity when they foster real or apparent biases in study design, data collection and analysis, adverse event reporting, or the presentation and publication of research findings. Even the appearance of a conflict between financial interests and professional responsibilities may weaken public confidence in the researcher's objectivity. The real and apparent risks posed by financial interests likewise have the potential to threaten public support for the research mission of academic institutions.

At the same time, a principled partnership between industry and academia is essential if we are to preserve medical progress and to continue to improve the health of our citizenry. The generous public support of scientific research in America's universities since World War II has been predicated on the expectation that scientific advancements will yield tangible public benefits - a robust economy, strong national security, and a healthy citizenry. Yet, public research support is, for the most part, purposefully limited in scope to basic research, and essentially ceases at the point at which scientific invention enters the pathway of product development. In biomedicine, with rare exceptions, it is the private sector, not academia, that develops diagnostic, therapeutic, and preventative products and brings them to market. At the crucial interface between innovation and development, researchers from academic medicine often play a critical role by conducting the early trans-lational research that gives rise to new products, and by testing these novel products for safety and efficacy.

Because the safety and welfare of human beings are at stake, financial interests in human subjects research are rightly the focus of intense scrutiny. Renewed attention to what are often termed "financial conflicts of interest" is occurring at a time when academic medical institutions are turning increasingly to private funds as a source of support for clinical research. Moreover, current federal policies encourage institutions to seek private investment as a vehicle for translating academic biomedical research into medically useful products. Under the

regulations implementing the Bayh-Dole Act of 1980, institutions and researchers are to share in the return on successful inventions arising from federally funded research.

Bayh-Dole is widely viewed as having created incentives for socially useful collaboration between academia and industry. The resulting commercialization of research harnesses the collective intellectual and creative talents of university faculty, speeds the development of new and improved therapies, stimulates regional economic growth, and contributes to the economic viability of research institutions. Notwithstanding these benefits, the increasing involvement of academics in commercially sponsored research places new demands on institutions to be scrupulous in crafting and enforcing their conflict of interest policies, and on Investigators to be diligent in adhering to them.

Institutional Conflicts of Interest

Any perception that an institution has a conflict of interest, especially in research with human subjects, weakens public support for research funding. The USF Health Conflict of Interest Committee ("COI Committee") will review both management systems as well as potential conflicts by individuals in positions of authority.

Specifically, the management of the institution's investments and licensing must be separated from the oversight of research. In some cases, investments should be managed by a separate foundation, such as the USF Research Foundation and USF Foundation, Inc. where management of financial interests in the research occurs within the university, special review must determine the potential for a conflict of interest.

When individuals in authority have a financial interest in a research project, they must disclose all relevant circumstances to a superior, and the COI Committee should review those circumstances. **If any conflicts of interest cannot be eliminated through recusal, or managed effectively via a strategy approved by the COI Committee, the research should not be conducted within or under the auspices of the institution.**

All USF Health officials in positions of oversight over research (chairs, associate deans, deans, associate vice presidents, vice president) should complete an annual disclosure of any potential conflict of interest, using the same form as Investigators. This form should be submitted to a superior and to the COI Committee.

Conflicts of Interest in Clinical Research (Involving Human Subjects)

The University and its faculty, staff, and students who conduct research involving human subjects must commit to the safety and welfare of those subjects and the integrity of the research above their own financial interests or the pursuit of personal gain. The safety and welfare of human subjects, institutional integrity and the public trust are the researcher's highest priority. Any conflict that threatens these objectives must be eliminated or strictly managed. Human subjects research is not a right, but a privilege. This privilege imposes certain obligations on the researcher and the University.

Accordingly, it is the policy of this University to regard all significant financial interests in human subjects research as potentially problematic and, therefore, as requiring strict scrutiny. This policy establishes the rebuttable presumption that an individual who holds a significant financial interest in research involving human subjects may NOT conduct such research. The intent is not to suggest that every financial interest jeopardizes the welfare of human subjects or the integrity of research, but rather to ensure that 1) any and every financial interest that might give rise to the perception of a conflict of interest is reported and systematically reviewed, and 2) that the conduct of human subjects research by financially interested individuals is limited to those situations in which the circumstances are compelling. The presumption against significant financial interests in human subjects research applies whether the research is funded by the University, any other public agency, a non-profit entity, or a commercial sponsor, and at every site where the research may be carried out.

In the event of compelling circumstances, an individual holding significant financial interests in human subjects research may be permitted to conduct the research. Whether the circumstances are deemed compelling will depend in each case upon the nature of the science, the nature of the interest, how closely the interest is related to the research, and the degree to which the interest may be affected by the research. When the financial interest is directly related to the research and may be substantially affected by it, the risk is greatest and the bar must be high.

If the research proposal involves research with human subjects, any significant financial interests associated with the research proposal must be reviewed by the COI Committee **prior** to final IRB approval of the research. COI Committee findings and determinations should guide the IRB's review of any research protocol or proposal, and the IRB may require additional safeguards or demand reduction or elimination of the financial interest. Between these two committees, the more stringent determination will be dispositive.

Conflicts of Interest in Science/Research (Not Involving Human Subjects)

Conflict of interest in research refers to situations in which financial or other personal considerations may compromise, or have the appearance of compromising, an Investigator's professional judgment in conducting or reporting research. The bias such conflicts may conceivably impart not only affects collection, analysis and interpretation of data, but also the hiring of staff, procurement of materials, sharing of results, choice of protocol, and the use of statistical methods.

At the crucial interface between scientific innovation and product development, academic researchers often play a critical role by conducting early translational research that gives rise to new products, and by testing these novel products. The opportunity for researchers to receive financial rewards from these endeavors is not intrinsically unacceptable, as long as this opportunity does not adversely influence scientific decision-making or interfere with the researcher's responsibility to the University.

Basic researchers should consider the potential effect that having a financial relationship of any kind with a commercial sponsor of a study might have. Relationships that lead an Investigator to prefer one outcome to another may influence an Investigator's judgment and behavior. All aspects and types of relationships need to be considered, including such clear-cut conflicts as financial incentives, serving as a paid consultant or speaker on behalf of a commercial sponsor, and less obvious ones such as non-monetary inducements or rewards to Investigators or their family members.

It is not possible to completely eradicate the potential for conflict of interest because there are certain rewards that are inherent in the structure of our research enterprise. Such rewards may be completely unrelated to relationships with industry or private sponsorship. For example, positive research results per se may contribute to opportunities for publication, promotion, tenure, grant renewals, and so forth. In addition, positive results are often more gratifying and lead to greater personal satisfaction than negative outcomes. In a sense, these influences can be as much a source of conflict in search for truth as interests of a pecuniary nature. But kept in perspective, such incentives are not inherently bad and are indeed the motivating forces for diligent scientists. Such conflicts become detrimental when the potential rewards, financial or otherwise, cause deviation from absolute objectivity in the design, interpretation, and publication of research activities, or in other academic and professional decisions.

Conflicts of interest also have the potential to bias other aspects of academic life, particularly when Investigators are in a position to set University or hospital policies, manage contracts, select equipment and supplies, involve students in sponsored projects, or have other administrative roles in which objectivity and integrity are paramount. In addition to these conflicts that occur at the faculty or individual level, there are also conflicts that may occur at the institutional level.

Individual conflicts of interest in research arise in large part because of the interplay between a faculty member's personal and financial interests and the opportunity to conduct externally-funded research. There is an inexhaustible matrix of situations in which faculty may find themselves, and it would be impossible for this document to provide a comprehensive list.

Conflict of interest in research not involving medical research will be managed according to the University's Policy on Conflicts of Interest in Research.

Pre-Clinical Research

Of special concern is basic research that may be pre-clinical in nature. Basic research, which will eventually give rise to clinical research, should be the subject of even more careful management and scrutiny. Leaders in a field of research may engage in pre-clinical research in that field and should be particularly attuned to conflicts of interest. For example, basic research results which will be the basis for clinical research should be independently confirmed to avoid future questions about research integrity or human subject safety. Such researchers have an independent responsibility and should take special care to ensure that such research is free of bias.

Conflict of Commitment

Appointment as a faculty member of this University confers the privilege and obligation to pursue teaching, research, scholarship, clinical care and service (whichever are appropriate to the position held). University employees owe their primary professional allegiance to the University, and their primary commitment of time and intellectual energies should be to these activities that are associated with their University employment.

A University appointment also conveys an obligation for a faculty member to have a significant presence on the University campus (or at affiliated institutions), to fulfill primary obligations to the University, to be accessible to students and staff, and to be available to other University employees, patients or affiliates throughout each semester of the faculty member's appointment, unless the department chair and/or dean has granted specific prior approval for absences that would interfere with accomplishing academic responsibilities. The specific responsibilities and professional activities that constitute an appropriate and primary commitment should be based on a general understanding between the employee and his or her department chair, dean or supervisor and may differ as among colleges, departments and disciplines.

Even with such understandings in place, however, attempts of employees to balance University responsibilities with outside activities – such as consulting, public service or pro bono work – can result in conflicts regarding allocation of time and energies. Conflicts of commitment usually involve issues of time allocation.

Time Allocation between University Duties and Outside Interests

Certain faculty assignments have specific accountability relative to time commitments. However, for the remainder of a faculty member's academic pursuits, there is no universally applicable standard or formula for determining appropriate levels of faculty effort with respect to allocation of time that is recognized by this University. It is the philosophy of the University that a system of precise time accounting is incompatible with the inherent character of the work of a faculty member. Outside activities may be pursued 1) only after consultation with the employee's supervisor to determine the expectations of the supervisor regarding the fulfillment of the employee's primary commitment of time, presence and objectives and 2) as long as the employee's commitment to the University have been fulfilled.

In sum, employees who wish to engage in outside activities should:

- Fully disclose the outside activity in the manner described in this policy,
- Meet with supervisor to determine supervisor's expectations regarding the employee's primary commitment of time, presence, and objectives,
- Assure that research, teaching, and public service obligations to the University are fully met,
- Abide by restrictions on the type and amount of outside activity as determined by the Designated University Official,
- Abide by commitments of effort as specified in contractual research agreements and grant applications, and
- Be discriminating in the selection of outside commitments, regardless of whether they are professional or non-professional in character, and regardless of whether the obligation is to be discharged in "off hours" or during vacation.

Conflict of Interest with University Employment

A conflict of interest with University employment may or may not involve a conflict of commitment. Whereas a conflict of commitment primarily relates to issues of time allocation, a conflict of interest can occur whenever there is a divergence between an individual's private interests and his or her professional obligations to the University such that an independent observer might reasonably question whether the individual's professional actions or decisions are determined by considerations of personal gain, financial or otherwise. A conflict of interest depends on the situation, and not on the character or actions of the individual.

Florida law prohibits an employee or public officer from doing business with his or her own agency. Florida law also prohibits conflicting employment or contractual relationships by public employees and officers. [Refer to the Florida Statutes](#) and click on Title X, Chapter 112, Part III, Section 112.313.

Nothing in this policy is intended to discourage an employee from engaging in outside activity in order to increase his or her professional reputation, service to the community, or income, subject to the requirements of this policy. As discussed above, an employee shall not engage in any outside activity that interferes with the full and competent performance of the employee's duties on behalf of the University.

An important mission of the University is technology transfer -promoting the public good by fostering the transfer of knowledge gained through University research and scholarship to the private sector. The University accomplishes this mission in part through faculty consulting and the commercialization of technologies derived from faculty research. It is appropriate and consistent with the University's mission that faculty be rewarded for their participation in these activities through consulting fees and sharing in royalties resulting from the commercialization of their work. However, it is wrong for an individual's actions or decisions made in the course of his or her University activities to be determined by considerations of personal financial gain. One purpose of this policy is to assist faculty and other employees in identifying areas where personal financial gain may influence one's objectivity and to provide a mechanism to manage those situations to eliminate possible bias associated with such inevitable conflicts of interest. Identification and management of conflicts is essential because not doing so may subject the professional objectivity and ethics of the individual to public criticism and reflect negatively on the University.

USF is an institution of public trust; employees must respect that status and conduct their affairs in ways that will not compromise the integrity of the University.

Conflicts of interest can also compromise a faculty member's academic performance. It is expected that faculty will foster an atmosphere of academic freedom by promoting the open and timely exchange of results of scholarly activities, ensuring that their advising of students and postdoctoral scholars is independent of personal commercial interests, and informing students and colleagues about outside obligations that might influence the free exchange of scholarly information between them and the faculty member.

Reporting and Review of Conflicts of Commitment and Conflicts of Interest

Requirement for Reporting Conflicts of Interest in Research

1. Timing and Scope of Reporting Responsibilities

Any University employee who is responsible for the design, conduct, or reporting of a research project which is conducted under the auspices of the University must report financial or other interests that are, or may be perceived to be, related to the project.

Investigators must fully report all interests for each research proposal at the time the proposal is submitted to the Investigator's department committee or hospital committee.

Investigators must provide updates of such interests on an annual basis and/or whenever they acquire new interests.

2. How and What To Report

It is the responsibility of each Health-Affiliated Individual to report conflicts of interest, regardless of the magnitude, appropriateness, time or location of the activity. All financial interests must be reported, whether or not the financial interest reaches the "significant financial interest" threshold defined in this policy, or any other threshold established by state or federal law.

The following financial interests **MUST BE REPORTED PRIOR TO ENGAGING IN THE RESEARCH:**

- Anything of monetary value, including, but not limited to, salary or other payments for services (e.g. consulting fees or honoraria);
- Equity interest (e.g. stocks, stock options, or other ownership interests);
- Intellectual property rights (e.g. patents, copyrights, and royalties from such rights);

Any other related interests or activities of the Investigator that possibly could affect, or be perceived to affect, the results of the research or educational activities funded or proposed for funding. The Investigator's interests are related to a research project if the work to be performed under the project, or the results of such work, can be expected to have an impact on the Investigator's interests. Such relationships include project subcontracts, leases, and purchases.

The following interests and activities are considered "significant financial interests" and will be reviewed by the COI Committee prior to approval of the research project:

- a. **Income** including salary, consulting payments, honoraria, reimbursement of expenses, royalty payments, dividends, or any other payments or considerations from a single business entity or their nonprofit affiliate entity exceeding \$10,000 per annum or \$50,000 over the course of the study and one year thereafter when aggregated for the Investigator. [The amounts stated are based on current FDA rules and may be amended from time to time.]
- b. **Equity** in the form of stock, stock options, real estate, or any other investment of ownership representing more than 5% interest for any one entity when aggregated for the Investigator. [The percentages stated are based on current FDA rules and may be amended from time to time.]
- c. A **Position** as director, officer, partner, trustee, or member of board of directors of any business entity.
- d. An interest in **Intellectual property** in which the property is held by a party other than the University.

The required report should be made on the Financial Interest Disclosure form (Appendix B) and submitted by the Investigator to the Designated University Official.

3. Submission of Form and Review by Institution Official

Financial Interest Disclosure forms for all Investigators shall be submitted to the Responsible Institutional Official for review upon submission of the research proposal to the Designated University Official or the Principal Investigator's department committee or hospital. The Responsible Institutional Official will review the form and may discuss with the Investigator any potential conflicts before making a final determination regarding the management, reduction or elimination of the conflict or apparent conflict. If the research involves human subjects, the matter will be forwarded to the COI Committee for review and determination of whether compelling circumstances exist to rebut the presumption that the Investigator may not conduct the research. The Investigator will be advised of the determination.

4. Review by COI Committee

If the Investigator disagrees with the determination of the Responsible Institutional Official, or if the research involves human subjects, the Responsible Institutional Official shall submit the Financial Interest Disclosure form and any relevant documentation to the COI Committee for consideration and resolution through management, reduction or elimination of the conflict or apparent conflict. The COI Committee's determination shall be final if the research does not involve human subjects. If the research involves human subjects, the IRB must also approve the research and the more stringent determination will be dispositive. The Investigator will be advised of the determination.

5. Special Considerations Involving Human Subjects Research

As a general rule, a financially interested individual may not conduct the human subjects research in question. This rule is not intended to be absolute: a financially interested individual may rebut the presumption by demonstrating facts that, in the opinion of the COI committee, constitute compelling circumstances. The individual would then be allowed to conduct the research under conditions specified by the COI committee and approved by the responsible IRB.

Compelling circumstances are those facts that convince the institution's COI committee that a financially interested individual should be permitted to conduct human subjects research. When considering a request by a financially-interested individual to conduct human subjects research, the circumstances that the COI committee should evaluate include the nature of the research, the magnitude of the interest and the degree to which it is related to the research, the extent to which the interest could be directly and substantially affected by the research, and the degree of risk to the human subjects involved that is inherent in the research protocol. The committee should also consider the extent to which the interest is amenable to effective oversight and management.

When the financial interest is directly related to the research and may be substantially affected by it, (e.g., an equity interest in a start-up company that manufactures the investigational product) the risk is greatest and the bar must be high; however, even direct and potentially lucrative financial interests may be justified in some circumstances. For example, when the individual holding such interests is uniquely qualified by virtue of expertise and experience and the research could not other-wise be conducted as safely or effectively without that individual, he or she should be permitted the opportunity to rebut the presumption against financial interests by demonstrating these facts to the satisfaction of the COI committee. The COI committee might approve the involvement of such an individual in the research, subject to conditions that ensure effective management of the conflict and credible oversight of the research.

At a minimum, the COI Committee shall require that the existence of any significant financial interest held by the Investigator and the institution be disclosed

1. in the research consent forms. The precise wording of the disclosure in the consent form should be determined by the IRB, but should include an explanation of the fact that the financial interest in question has been reviewed by COI committee, approved subject to oversight, and determined by both COI Committee and the IRB not to pose any additional significant risk to the welfare of research subjects or the integrity of the research. The disclosure statement should also indicate that all approving authorities have disclosed any conflict and that additional information will be provided to research subjects upon request.
2. to state and federal officials if required by statute or regulation.
3. to research sponsors or granting agencies.
4. to the editors of any publication to which the Investigator submits a manuscript concerning the research.
5. to trainees and prospective collaborators; and
6. in any substantive public communication of the research results, whether internal or external, oral or written.

In addition, the COI Committee shall prohibit payments to the Investigator from the sponsor or University which payments are conditioned upon a particular research result or are tied to a successful research outcome. Payments for subject enrollment or referral of patients to research studies should be permitted only to the extent that such payments 1) are reasonably related to the costs incurred, as specified in the research agreement between the sponsor and the Investigator/institution; 2) reflect the fair market value of the services performed and 3) are commensurate with the efforts of the individual performing the research.

Additional considerations of the COI Committee for review of human subjects research shall be as set forth more specifically in the COI Committee manual.

6. Special Considerations Involving Institutional Conflicts of Interest

Financial relationships between the institution, its officials, and the agency sponsoring a research project warrant the highest degree of scrutiny by the COI Committee:

- when the institution is entitled to receive royalties from the sale of the investigational product,
- when the institution has obtained an equity interest in a non-publicly traded sponsor,
- when, through technology licensing activities or investments, the institution has obtained an ownership interest or an entitlement to equity of greater than \$100,000 in value, in a publicly-traded sponsor,
- when institutional officials hold a significant financial interest in the commercial research sponsor or the investigational product,
- when other special circumstances arise, including times when the institution has received substantial gifts from a potential commercial sponsor of human subjects research.

Requirements for Reporting of Outside Activity

1. Generally

- An employee shall not engage in any outside activity that interferes with the full and competent performance of the employee's duties on behalf of the University.
- An employee engaging in any outside activity shall not use the facilities, equipment, or services of the University in more than an incidental manner in connection with such outside activity without prior written approval of the Vice President for USF Health. Such approval may be conditioned upon reimbursement for the direct costs resulting from the use thereof.

2. Timing and Scope of Reporting Responsibilities

All employees who propose to engage in any outside activity which the employee should reasonably conclude may create a conflict of interest are to complete a USF Health Report of Outside Activity via [ROAD](#) and submit it to the Designated University Official:

- Upon initial employment with the University
- Prior to engaging in any new outside activity
- Annually thereafter for continuing outside activity (with the reporting period being July through June 30)
- Any time there is a significant change (e.g., nature, extent, funding) to previously reported and approved outside activities.
- Any outside activity in which the employee is currently engaged but has not previously reported, shall be reported within (45) days of the effective date of this policy. Failure to report outside activity as required pursuant to this policy will constitute grounds for disciplinary action.
- The University recognizes that certain matters that are the subject of outside activities may be confidential, for example, matters which are exempt from disclosure pursuant to sections 240.299 and 240.241 of the Florida Statutes relating to trade secrets, potentially patentable material and other proprietary information. Confidential aspects of outside activities need not be disclosed in the Outside Activity form, but the financial and commitment aspects of the activity should be reported.
- Institutions and Health-Affiliated Individuals bear a shared responsibility for the oversight of conflicts of commitment.

3. What Outside Activities to Report

The following outside activities **MUST BE REPORTED AND APPROVED PRIOR TO ENGAGING IN THE ACTIVITY:**

- outside activities in which there is more than an incidental use of University facilities, equipment, and/or services.
- 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.
- management, employment, consulting, and contractual activities with, or ownership interests in, a business entity (or state agency) that 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.
- management, employment, consulting, and other contractual activities with, or ownership interest in, a business entity which competes with the University.
- candidacy for public office.
- required use of books, supplies, equipment, or other instructional resources at the University of South Florida when they are created or published by the employee or by an entity in which the employee has a financial interest.
- professional compensated activities, including, but not limited to consulting activity related to the employee's field of discipline, teaching at another institution, participating in an activity in which an honorarium in excess of travel expenses is to be received, and employment as an expert witness.
- business activities, including membership on an advisory council, scientific advisory board, service on the board of directors or other management interests or positions, with regard to a business entity with activities in the same discipline or field in which the faculty or staff member is employed.
- 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 that supports the employee's research or training program at the University.

- outside activities and financial interests required to be reported under federal contract and grant regulations.
- other activities that the employee should reasonably conclude may create an actual or apparent conflict of interest, including a conflict of time commitments.

4. How To Report Outside Activities

The required disclosure should be made on the USF Health Report of Outside Activity annually and updated to report changes or additional activities.

- name of employing or contracting entity or person, or name of entity in which the financial interest is held, and nature of its business.
- 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.
- 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, location and anticipated dates of activity.
- any conditions of the activity which involve waiving or impairing the employee's or University's rights to intellectual property.
- use of University's equipment, facilities, or services in more than an incidental way in connection with the activity.
- number of other outside activities and financial interests previously filed for the contractual year.
- prior approval of the activity or financial interest in the previous contractual year, if applicable.

Other information may also be requested in order to assume a complete review of the activity if there are potential conflicts involved. All individuals have responsibility for the reporting powers and of assuring its proper management.

5. Submission of Outside Activity Form and Review by Designated University Official

Employees shall submit the completed USF Health Report of Outside Activity via [ROAD](#) to the Designated University Official within sufficient time to secure the appropriate approvals before engaging in any outside activity. The Designated University Official shall review the form and discuss the matter with the employee within fourteen (14) days of the employee's written notification. If the matter is unresolved following this discussion, the employee may refer the matter to the Dean of the College. The Dean shall review the matter within fourteen (14) days of the referral. If the matter remains unresolved, the employee may refer the matter to the Vice President for USF Health who shall determine whether the outside activity creates an unmanageable conflict of interest or otherwise interferes with the employee's University duties. The employee shall be notified in writing of the Vice President's determination within thirty (30) days of the date that the matter was referred to the Vice President.

The employee may engage in the outside activity pending the decision of the Vice President. If the Vice President determines that there is a conflict of interest or other interference with the employee's duties, the employee shall cease such activity immediately and turn over to the University any compensation earned therefrom.

6. Special Considerations for Outside Activity Involving Students, Trainees, Junior Faculty and Support Staff

Junior Faculty. Senior faculty may offer junior faculty opportunities for professional development through involvement in outside professional activities. However, senior faculty must not compromise their objectivity in evaluating their junior faculty in issues of promotion and tenure by virtue of outside professional activities in collaboration with junior faculty members, nor should senior faculty allow internal relationships with junior faculty to influence external relationships, expectations, or assignments. The Designated University Official should approve any new involvement or change in outside professional relations of senior and junior faculty after joint discussion with both senior and junior faculty concerned.

Students or Trainees. Part-time involvement of students or trainees in the outside professional activities of faculty may, under certain conditions, offer the potential for substantial benefits to the education of the student. In each case of such involvement, the faculty member should obtain prior approval from the Designated University Official after discussion with the Designated University Official and the student. In this context, involvement means any substantive activity, whether paid or unpaid.

In considering such arrangements, faculty should be guided by the need to avoid conflicts of interest and to avoid infringement upon the student's academic duties and rights. Generally, if the faculty member has a role in supervising the student's thesis or in supervising the work of the student as a graduate teaching assistant or instructor, such outside involvement should not be undertaken--thus avoiding potential conflicts of interest in the evaluation of the student's performance. If the faculty member does not have a role in supervising the student's thesis and/or the student's work as a teaching assistant or instructor, such involvement may be undertaken. If the outside work is related to the student's thesis, special care should be taken to avoid conflict.

If faculty members are already associated with students in outside professional activities, they should disqualify themselves from becoming research supervisors, academic program advisors, or examiners for an advanced degree of those students. Within a USF research laboratory or academic unit, faculty members should take care not to give the impression of favoritism to those students with whom they are associated in outside activities. Generally, full-time research assistants should not be involved in outside professional activities of faculty - both to avoid conflicts of interest and in light of the obligations of full-time research assistants. A part-time research assistant may engage in such activity if the outside work is not thesis-related and if the faculty member is not his or her supervisor.

Support Staff. Support staff play an important role in assisting the faculty with their USF teaching, research, and administrative activities. It may also be appropriate for support staff to assist faculty members in their outside professional activities, depending upon the nature and extent of the support staff involvement. Such involvement, however, is a potential source of conflict between faculty and their support staff. It is especially important, therefore, that faculty discuss with their support staff the appropriateness of any such support activities requested. Any special arrangements for providing support for faculty outside professional activities, including compensation from non-USF sources, must be acceptable to all the parties involved. If support staff will be compensated for work on outside professional activities, such work must be performed on the staff member's own time and not during hours compensated by the University.

Guidelines defining appropriate support are given below; faculty members should discuss any circumstances that do not obviously meet these guidelines with the Designated University Official.

- It is normally appropriate for support staff to assist faculty in their professional public service activities, i.e., those professional activities in which faculty provide a service to institutions other than the University for public benefit, and in which compensation is incidental. If the effort required to provide such support is likely to be substantial and long term, however, a faculty member should review the circumstances with his or her Designated University Official.
- It may also be acceptable for support staff to provide limited assistance to faculty in other types of outside professional activities. Any assistance provided for such outside activities must not be in conflict with the faculty and support staff's responsibilities to the University.

- Faculty may not require support staff to perform duties related to the faculty member's personal and nonprofessional activities.

7. Use of University Resources in Outside Activity

Employees may not use University resources, including facilities, personnel, equipment, or confidential information, except in a purely incidental way, as part of their outside activities or for any other purposes that are unrelated to the education, research, scholarship, and public service missions of the University. When applicable, complete the Use of University Equipment, Facilities and Services Form via [ROAD](#).

Under special circumstances (e.g., start-up phase of University-based company) use of University resources may be permitted with appropriate reporting to and discussion with the Designated University Official and may be conditional upon reimbursement for direct and indirect costs resulting from such use.

Definitions (Appendix A)

Compensation means any salary; honorarium; benefits; services; fees; milestone payments; bonuses; equity interests and royalties; proprietary interests; warrants; grant funding; corporate underwriting; patent, trademark, copyright or license agreements commissions; payments; gifts; real property; the use of real property; tangible or intangible personal property; the use of tangible or intangible personal property; preferential rates or terms on a debt, loan, goods or services; or anything of value.

Conducting Research means, with respect to a research protocol, designing research, directing research, or serving as the principal investigator, co-investigator or investigator, enrolling research subjects (including obtaining subjects' informed consent) or making decisions related to eligibility to participate in research, analyzing or reporting research data, or submitting manuscripts concerning the research for publication.

Conflict of Commitment means a conflict of interest with University employment that primarily relates to issues of time allocation.

Conflict of Interest is any conflict between the private interests of the employee and the public interests of the University, the University Board of Trustees, The Florida Board of Education or the State of Florida, including conflicts of interest specified under Florida Statutes OR any activity that interferes with the full performance of the employee's professional or instructional responsibilities or obligations.

Conflict of Interest in Research refers to situations in which financial or other personal considerations may compromise, or have the appearance of compromising, an Investigator's professional judgment in the conduct, evaluation or reporting of research.

Consulting means professional activity related to the person's field or discipline, where a fee-for-service or equivalent relationship with a third party exists.

Designated University Official (herein referred to a "Official") is the responsible administrative official with immediate supervisory authority over the employee. Normally, the Official will be the department chair. For administrative units in which there are no departments, or if the employee is a department chair, the Official will be the unit Director or Dean. For Directors and Deans, the Provost or other appropriate Vice President will serve as the Official.

Disclosure means a release of relevant information about significant financial interests in human subjects research to parties outside the institution's COI review and management processes (e.g. to research subjects or journal editors).

Financial Interest means any **compensation** which is accepted by the **employee** or that which is paid or given to the employee directly, indirectly, or in trust by any other means.

Financially Interested Individual means an individual who holds a significant financial interest that would reasonably appear to be affected by the individual's human subject research.

Health-Affiliated Individual means USF Health officers, faculty, staff, students and committee members involved in the academic, clerical or managerial mission of the University.

Human Subjects Research includes all research meeting the definition of "research" performed with "human subjects" as these terms are defined in the federal Common Rule (45 C.F.R. Part 46 and 21 C.F.R. Part 56), regardless of the source of research funding or whether the research is otherwise subject to federal regulation. In the event that the Common Rule definitions of "human subjects" or "research" are modified through rulemaking, any such revisions shall apply for the purposes of this guidance.

Institutional Conflict of Interest may occur whenever the financial interests of the institution, or of an institutional official acting within his or authority on behalf of the institution, might affect—or reasonably appear to affect—institutional processes for the conduct, review, or oversight of research, especially human subjects research.

Investigator means the principal investigator, co-investigator or any other person who is responsible for the design, conduct, evaluation, patient care, and/or reporting of research for the proposed or ongoing project. For the purposes of the requirements of the subpart relating to financial interests, "Investigator" includes the Investigator's relatives and trusts or any other financial vehicle designed to obfuscate ownership.

Outside Activity shall mean any private practice, private consulting, or other activity, compensated or uncompensated, which is not part of the employee's University duties and for which the University has provided no compensation.

Rebuttable Presumption Against Financial Interests in Human Subjects Research means the institution will presume, in order to assure that all potentially problematic circumstances are reviewed, that a financially interested individual may not conduct the human subjects research in question. This rule is not intended to be absolute: a financially interested individual may rebut the presumption by demonstrating facts that, in the opinion of the COI committee, constitute compelling circumstances. The individual would then be allowed to conduct the research under conditions specified by the COI committee and approved by the responsible IRB.

Relative or Related Persons are those related to each other in one of the following ways: husband, wife; parent; child; brother; sister; spouse of a child, brother or sister or parent, child, brother or sister of a spouse.

Reporting means the provision of information about significant financial interests in human subjects research by a covered individual to responsible institutional officials and to the institutional COI committee, or the transmission of such information within institutional channels (e.g., from the COI committee to the IRB).

Responsible Institutional Official means a Dean, Provost, CEO, or other institutional official who is responsible for the oversight of conflicts of interest within the institution.

Responsible IRB is the institutional review board (or boards) with jurisdiction over the research as specified in the multiple projects assurance (MPA) (or the federal-wide assurance (FWA)) that the institution has provided the U.S. Department of Health and Human Services, or as otherwise established under DHHS or DA regulation or policy.

Significant Financial Interests means

[USF Policies on the General Counsel's Home Pages](#) **Income** including salary, consulting payments, honoraria, reimbursement of expenses, royalty payments, dividends, or any other payments or considerations from a single business entity or their nonprofit affiliate entity exceeding \$10,000 per annum or \$50,000 over the course of the study and one year thereafter when aggregated for the Investigator. [The amounts stated are based on current FDA rules and may be amended from time to time.]

Equity in the form of stock, stock options, real estate, or any other investment of ownership representing more than 5% interest for any one entity when aggregated for the Investigator. [The percentages stated are based on current FDA rules and may be amended from time to time.]

A **Position** as director, officer, partner, trustee, or member of board of directors of any business entity.

An interest in **Intellectual property** in which the property is held by a party other than the University.

Related University and USF Health Policies

[USF Policies](#) on the General Counsel's Home Pages

University Copyright Policy	0-105
Candidacy of Employees for Public Office	0-012
Use of University Name and Symbols	0-215
Conflicts of Interest in Sponsored Research	0-309
Statement of Policy Regarding Inventions and Works	0-300
Misconduct in Research	0-301
Research and Research Grants	0-304
Use of University Space (All-Inclusive)	0-505
Appropriate Use of Information Technology Resources	0-502
USF Faculty Rule, Faculty Ethical Obligations: Conflicts of Interest and Outside Employment; Employment of Relatives; Seeking or Holding Public Office	10.107

Federal Authority

FDA Regulations, "Financial Disclosure By Clinical Investigators" (21 CFR Part 54) (April 1, 2002)

<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/showCFR.cfm?CFRPart=54>

PHS Regulations, "**Responsibility of Applicants for Promoting Objectivity in Research for Which PHS Funding Is Sought**" (42 CFR Part 50, 50.601-50.607) (July 11, 1995)

<http://grants1.nih.gov/grants/guide/notice-files/not95-179.html>

NSF Policy on Conflict of Interest (NSF Grants Policy Manual, Section 510)

http://www.nsf.gov/pubs/manuals/gpm05_131/gpm5.jsp#510

State Authority

Florida Statutes, Section 112.313, "Standards of Conduct for Public Officers and Employees of Agencies" (2001)

[Refer to the Florida Statutes](#) and click on Title X, Chapter 112, Part III, Section 112.313.

Other References

FDA Guidance For Industry, "Financial Disclosure By Clinical Investigators" (March 20, 2001)
<http://www.fda.gov/downloads/regulatoryinformation/guidances/ucm341008.pdf>


AAU Report on Individual and Institutional Conflict of Interest (October 9, 2001)
http://www.aau.edu/policy/COI_reports.aspx?id=10094

NIH Guide, "Objectivity in Research" (July 14, 1995)
<http://grants1.nih.gov/grants/guide/notice-files/not95-179.html>

NIH Guide, "Financial Conflict of Interest and Research Objectivity; Issues for Investigators and Institutional Review Boards" (June 5, 2002)
<http://grants1.nih.gov/grants/guide/notice-files/NOT-OD-00-040.html>

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- [Careers \(Healthcare\)](#)
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