

UNIVERSITY OF SOUTH ALABAMA

INSTITUTIONAL CONFLICT OF INTEREST POLICY

1. PREFACE

This policy is established to provide appropriate institutional safeguards to sustain an environment where sponsored projects, dedicated gifts, research, scholarship, entrepreneurial endeavors, and technology transfer are carried out responsibly, and in so doing foster an culture of transparency and integrity.

The University engages in relationships with a range of companies that may lead to financial benefit for the University in many forms, including royalty payments, other payments and equity from licensing intellectual property, sponsored education and research agreements, dedicated gifts and purchasing. Relationships with commercial entities are generally part of customary educational, research, and business activities, and consequently will lead in some cases to conflicts of interest. Given the scope of University activities, the variation in its relationships, and the pursuit for the University to act as good stewards of its funds, it is inherent that University relationships and potential institutional conflicts of interest are unavoidable. The intent of this Policy is not to restrict or discourage such relationships, but, rather to manage them so they do not compromise, or reasonably appear to compromise, the safety and integrity of the University's mission.

2. POLICY

The University policy on Institutional Conflicts of Interest applies to Employees and Covered Entities of the University of South Alabama as defined below in Section 3. This policy concerns conflicts that arise from the University's financial relationships with external entities such that the University must conduct its business free of improper influence resulting from external institutional financial relationships. The goal of this document is to raise awareness of the issues and situations that should be disclosed, reviewed, and managed on behalf of the University by the individuals who serve as its leaders and administrators. Each institutional financial interest that presents the potential for conflict of interest should be disclosed to the Supervisor and/or the Vice President of the division, within which, that activity would occur as noted in Section 5.1.

3. DEFINITIONS

3.1 Institutional Conflict of Interest (ICOI). A situation which arises when financial interests of the University, or a University official acting within his/her authority on behalf of the University, may influence or appears to influence the research, education, clinical care, business transactions, or other activities of the University.

3.2 Equity. An interest in a business consisting of any stock, stock option, or similar ownership interest in such business.

3.3 University Officials (hereinafter referred to as *Covered Individuals*).

For purposes of this Policy, Covered Individuals include those administrators who are in a position to make or significantly influence decisions on behalf of the University involving the following:

- the use of University resources, including decisions involving expenditures, purchasing, investments, equity and technology transfer;
- the conduct of research, in particular research involving human subjects
- the execution of grants and contracts, or

- the licensing of University intellectual property to external parties

Based on the foregoing, Covered Individuals include but are not limited to:

- University President and Chief of Staff
- Board of Trustees
- University Vice Presidents and Associate/Assistant Vice Presidents
- Deans, Vice/Associate/Assistant Deans
- Institute Directors

3.4 Covered Entities. This term refers to the following sites:

- University campuses
- USA Medical Center
- USA Children and Women's Hospital
- USA Health Systems
- Mitchell Cancer Institute

4. AREAS OF INCREASED RISK FOR INSTITUTIONAL CONFLICTS OF INTEREST

Institutional financial conflicts of interest can occur in various contexts across campuses, but generally they concern the University and the public if they have a significant potential to compromise the University's mission, regardless of the field or context.

4.1 Institutional Financial Conflict of Interest Consists of Two Major Types:

- 4.1.1.** Potential Conflict of Interest involving University equity holdings or a royalty arrangement related to Sponsored Programs, and
- 4.1.2.** Potential Conflict of Interest involving University officials who make decisions with institutional-wide implications, which can include department heads and center and institute directors, in addition to senior management

4.2 University Intellectual Property. The University has a legal duty to manage its intellectual property. In accordance with University policies, the University has the authority to license and receive compensation for its intellectual property. In certain cases, the entity licensing the intellectual property may have other research, financial or business relationships with the University that could raise a conflict.

For example, institutional conflicts of interest may arise when an entity both licenses University intellectual property for a commercial purpose and also sponsors University research on the intellectual property at issue. When the University is conducting research on its own intellectual property such research and related findings may also be subject to challenge. Even when the individual researcher does not have a financial interest in the intellectual property, the knowledge that the University, campus or research laboratory stands to gain financially from successful development of a licensed technology can influence the direction of related research or other University or campus activity, the objectivity of research, the dissemination of results and the allocation of resources among competing projects and activities.

- 4.2.1. Equity and Licensing Arrangements.** The University owns stocks and other forms of equity in companies as part of its investment holdings and endowment portfolio. A potential institutional conflict may occur when the University licenses an invention to an entity that also has a financial or business relationship with the University. For example, the University has obtained a significant ownership interest or an entitlement to significant equity in a company that is (i) the sponsor of research at the university, or (ii) the manufacturer or distributor of a

product that is either studied or tested in research at or under the auspices of the University, or based at least in part on technology developed here. Direct investments by the University or its management company in University-related start-up companies warrant sensitivity to ensure that no violations of this Policy occur as a result of such investments.

The Vice President for Research, in consultation with the University Conflict of Interest Committee, is responsible for putting in place and maintaining appropriate office policies and procedures to oversee the strategies under which the Office of Technology Transfer negotiates equity positions in licensing agreements consistent with the University's equity policy.

4.3 Gifts from Companies. Potential conflicts may arise when a company that has a financial or business relationship with the University also donates a gift to the University. For example, if the University is offered or has received significant gifts (including, but not limited to, gifts in kind, discounts, fellowships, and unrestricted educational grants) from a company or a foundation established by or closely affiliated with a company that is (i) sponsoring or offering to sponsor research at the University, or (ii) the manufacturer or distributor of a product that is either studied or tested in research at or under the auspices of the University, or based at least in part on technology developed here.

4.4 Purchasing. A vendor or potential vendor also has a financial or business relationship with the University or campus. A conflict, or the appearance of a conflict, may arise in purchasing situation when a covered individual as defined under this policy or University official has a financial, personal, or business interest in a vendor whose products or services provided are considered for purchase.

4.5 University Officials with Personal Conflicts of Interest. Due to supervisory and institutional decision making functions, University officials encounter conflict of interest situations beyond those confronted by most faculty or other administrators. As they often do not conduct research, teaching or faculty service in their capacity as an administrator, however, may be in a position to influence how they are conducted and reported. Their business and financial relationships with external entities shall be disclosed to prevent any real or perceived institutional conflicts of interest.

4.6 Human Subjects Research. Research involving human subject's research requires additional oversight because of the potential to compromise the health or safety of human subjects. The financial interests of senior University Officials must not affect, or reasonably appear to affect, the design, conduct, reporting, review or oversight of human subjects research carried out in USA's department(s) over which they have authority or whose access to University resources are under their direct oversight.

5. DISCLOSURE AND REVIEW PROCESS

Disclosures should be filed on a case by case basis using the *Institutional Conflict of Interest Disclosure* form. Due to the variety and complexity of University activities, no set of guidelines can anticipate and deal with all possible scenarios. Therefore, a major responsibility for those who represent the University is to: (1) disclose conflict of interest situations when they arise, whether potential, apparent, or actual, and (2) seek direction at the appropriate levels on how to manage the situation appropriately.

5.1 Identify and disclose the potential conflict. Potential ICOI will be identified when University Officials report financial interests in an entity conducting business with the University in an area over which that University Official has direct supervision or decision-making responsibilities. Reports should be disclosed and documented by completing the *Institutional Conflict of Interest Disclosure* form and provide to their Supervisor and/or the Vice President of the division, within which, that activity would occur. As such, areas that involve fiscal or human resource matters must be disclosed to the Vice President for Financial Affairs and for research related activities to the Vice President for Research. Potential conflicts are also identified by employees or other individuals who are concerned about possible conflicts of interest and report those situations to their supervisors or other appropriate University Officials.

5.1.1. Royalties and Other Income

- Researchers conducting human subjects research will be asked when completing IRB applications if the proposed study evaluates directly or indirectly a University invention. If so, a copy of the application is reviewed by the Director, Research Compliance and Assurance. If warranted, the potential conflict will be elevated to the designated Vice President for review. The Office of Technology Transfer in preparation of exclusive license or option agreements check information about research sponsors, vendors and gift donors to determine if the potential licensee or start-up company also has other types of financial or business relationships with the University.

5.1.2. Start-ups and equity interests

- For conflicts of interest that could arise when the University is negotiating a possible equity interest in a start-up company, potential conflicts will be identified when the Office of Technology Transfer are developing agreements that include an equity interest in the new company. Additionally, there is no threshold if it is likely that that start-up company may sponsor the research at the University that involves human subjects. Before finalizing agreements, Sponsored Programs will be the point of contact for information on current and potential research projects.
- For conflicts that could arise when the University already holds equity in a company, the University typically avoids risks associated with this type of intuitional conflict by separating equity information and decision-making from the research enterprise. Employees in the position to directly influence the research, teaching or other activities do make decisions regarding these equity interests.

5.1.3. Purchasing.

- Purchasing Staff may identify potential conflicts as they participate in or review purchasing decisions. They refer the potential conflict to the Director of Purchasing and elevated to the designated Vice President for review. Employees or other individuals concerned about possible Institutional conflicts of interest in the purchasing context should report situations to University officials.

5.1.4. Gifts.

Identify the potential conflict:

- Through disclosures by Covered Individuals. Potential institutional conflicts of interest may arise if your department or area received a gift from a company that also sponsors research or supplies equipment or services to your area of oversight.
- Through situations reported to University officials by employees or other individuals concerned about possible conflicts of interest.

5.1.5. Human Subjects Research.

Direct financial interests of a University Official in an external entity which is sponsoring human subject's research or a financial interest specific to intellectual property that is the subject of human subjects research must be disclosed when an individual in the department for which he/she is the institutional leader proposing such research, as subject to the points described below. Direct financial interests include:

- Equity holdings that are held directly by the University Official, or his/her immediate family, but exclude (a) mutual funds for which the individual has no control over the investment decisions of the fund or (b) dollars for which the University Official does not actively manage. This individual should not participate in decision making regarding the purchase of or sale of individual stocks.

- Royalties (whether paid through USA or through another source).
- Payments for consulting, board service or other services and any other financial relationship that involves funds received by the company to the University Official.

5.1.6. Board of Trustees. Members of the Board of Trustees are governed by [Bylaws](#) such that Article VI contains conflict of interest policies to assist Board members in identifying, disclosing and minimizing conflicts. These Bylaws are accepted as policy for purposes of compliance with Institutional Conflict of Interest.

5.2 Review the potential conflict. Areas that involve fiscal or human resource matters are reviewed by the Vice President for Financial Affairs and for research related activities the Vice President for Research. The respective designated Vice President is responsible for evaluating the risk of an institutional conflict, consulting with individuals and offices as necessary. In the event of a conflict or any unresolved situations, the review will be elevated to the University Conflict of Interest Committee. This review will include determination of whether a management plan is appropriate and necessary. Additionally, the designated Vice President will implement and monitor post-approval compliance with its determination. The designated Vice President will share all reports of institutional conflicts of interests to the President and University Conflict of Interest Committee on an annual basis.

5.2.1. Review Criteria. Reviews must consider whether the financial or fiduciary interests disclosed in accordance with this policy affect or may potentially affect any of the following:

- Safety of human research subjects;
- Safety of patients;
- Integrity of research;
- Appropriate allocation of resources;
- Objectivity and independence of educational activities, including undergraduate, graduate, post-graduate, and continuing education;
- Objectivity in business and contracting decisions

5.3 Recommendation Process. The designated Vice President review of a specific case may result in one of four recommendations:

5.3.1. No Institutional Conflict: In cases resulting in a finding that there is no actual, potential, or perceived institutional conflict, the designated Vice President must communicate his/her decision to the appropriate individual(s) responsible for the activity and any University Official whose interest was at issue.

5.3.2. Manageable Institutional Conflict: In cases where the designated Vice President considers manageable, a recommendation of one or more management measures will be provided. Examples include, but are not limited to: (1) effective recusal from decision-making regarding the proposed arrangement by the financially interested University Official and disclosure of the recusal to the appropriate individuals to implement the recusal; (2) reduction in the magnitude of the financial interest; (3) disclosure of the financial interest in relevant publications, presentations, human subject consent forms, clinical procedure or other consent forms, educational material, etc., (4) oversight by a disinterested senior individual or committee, and/or (5) other measures as deemed appropriate.

5.3.3. Institutional Conflict in Human Subject Research: Primary consideration will be given to potential impact on the safety and welfare of human research subjects. In addition, the potential impact of real or perceived institutional conflict on the integrity or credibility of research data that could affect future clinical use will be considered carefully. As appropriate, the designated

Vice President review will be coordinated with and provided to the University's Institutional Review Board and Office of Research Compliance and Assurance for its consideration in exercising its responsibility for the protection of human research subjects.

- 5.3.4. Unmanageable Institutional Conflict:** In cases where the conflict is considered not manageable, the designated Vice President will report his/her recommendation to the appropriate recipient of the recommendation with written justification. In cases judged to involve an unmanageable institutional conflict, it is expected that the designated Vice President will make recommendations to eliminate conflicting financial interests where practical in ways that do not compromise the proposed research, professional, business transaction, or educational activity. Generally, the Institution should give precedence to activities that carry out Institutional missions over conflicting financial interests.

6.0 PROCEDURES FOR REPORTING CONCERNS AND MECHANISMS FOR REVIEW

Any University Official or employee who has concerns about the legitimacy of any relationship or activity on behalf of the University or its employees involving an external relationship should consult with his/her immediate supervisor or with other individuals or through other mechanisms, including voicemail, e-mail, mail or fax, provided for in the applicable University policy. If after examination of the situation is determined that a potential ICOI exists or the circumstances pose a concern for public perception of an ICOI, the matter should be referred to the designated Vice President of the division that involves the activity for investigation. As such, areas that involve fiscal or human resource matters must be disclosed to the Vice President for Financial Affairs and for research related activities to the Vice President for Research. In the event of a conflict in decision making, the matter will be referred to the University Conflict of Interest Committee.

Any act of retaliation or reprisal against an individual for reporting in good faith a potential ICOI or violation of this Policy shall be a violation of this Policy. Such violations will be dealt with through regular administrative process for violation of University policies.

6.1 Appeals. When an individual with a potential institutional conflict of interest also has an individual conflict of interest, the appeal process under the individual conflict of interest policy applies as defined in Section 7.6 of the policy on [University Conflict of Commitment/Financial Conflict of Interest](#).

Appendix - Examples of Institutional Conflicts of Interest

While there is no inclusive list of institutional conflicts of interest, some situations naturally create potential and actual institutional conflicts. The following list is offered as illustrations of situations which require attention.

- The University has a financial or business relationship with an outside entity and that entity seeks to influence the award or terms and conditions of a University contract, the direction review or dissemination of research, or the allocation of resources – regardless of the type of financial or business relationship.
- The University has a financial or business relationship with an external entity, and decisions about the activities related to the relationship may affect the financial or business interests of the University.
- A University Leader is in a supervisory or administrative position, and a decision on behalf of the University about a financial or business relationship with an external entity may directly affect the University Leader's personal financial interest in that outside entity.
- The University holds a financial interest in an outside entity and the University makes decisions regarding the financial and business relationship with that outside entity which directly affect its own financial interest in that entity.
- A University Leader is appointed to serve as an officer, director, or board member of an outside entity that has financial or business relationships with the University.
- The University invests funds with an outside entity and University Leaders approving the investment have a personal financial interest in the outside entity.

Source of Examples: University of North Carolina Institutional Conflict of Interest Policy