



UNIVERSITY OF
SOUTH ALABAMA

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Responsible Office: Office of Research
Compliance

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Conflict of Interest in Research Policy

1. Purpose

This policy establishes University of South Alabama guidelines to aid in the identification, evaluation and resolution of potential or real Financial Conflict of Interest related to University research activities. This Policy is intended to establish compliance with the rules adopted effective September 26, 2011 by the U.S. Public Health Service, *Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is Sought* [42 CFR Part 50, Subpart F] and the National Science Foundation Conflict of Interest Policies, Chapter V: Grantee Standards, Policies and Procedures Guide. These agencies require that grantee institutions adopt, maintain and enforce written policies pertaining to researchers' financial conflicts of interest.

While not addressed by this policy, the Alabama State Ethics Law, as well as other laws, regulations or policies, may also specifically define and limit the ability of Employees of the University to participate in certain activities. The University and its Employees are also subject to the provisions of the Code of Ethics for Public Officials, Employees, etc. as described in Chapter 25 of the Title 36, Code of Alabama, 1975 (the Alabama State Ethics Law). Therefore, it is the policy of the University that Employees of the University demonstrate, in all professional and research activities, that their primary obligation is to the University and the integrity of the research and that they adhere, in all instances, to the highest standards of ethical behavior.

2. Applicability

Conflict of Interest in Research policy applies to:

- 2.1 University employees (i.e., faculty, staff, students, trainees) who are responsible for the design, conduct, or reporting of research and scholarly activities* and any University faculty who are identified in a budget or who are acting as a consultant or collaborator in any:
 - 2.1.1 Externally supported activities for University programs, projects, activities and services;

2.1.2 Internally supported research activities for the benefit of an external entity (e.g. non-funded research projects where deliverables such as reports/data are provided to an external entity)

2.2 University faculty, staff or students who hold a financial interest or obligation in a company that is negotiating an agreement with the Office of Commercialization and Industry Collaboration for technology developed by the respective faculty, staff or student.

**Exceptions:*

Not included: Individuals who do not make independent decisions regarding the design, conduct, or reporting of the activity in question, and only work on or are engaged in the activity (for example, in most cases research assistants, undergraduate students and administrative support will not be considered responsible for the design, conduct, or reporting of activities of a research project). However, for PHS funded activities: collaborators or consultants are considered responsible for the design, conduct, or reporting of activities of a research project. For review and management of conflicts, the governing legal and policy requirements shall prevail.

3. Definitions

Business Entity. A Business Entity is defined as any corporation, partnership, sole proprietorship, firm, franchise, holding company, joint-stock company, receivership, real estate trust, or other legal entity organized for profit and non-profit entities that may provide support to employees as salary, consulting, or board compensation. The term does not include the University or any other entity controlled by the University. Business Entity does not include federal, state, or local government agencies, institutions of higher education as defined at 20 U.S.C. 1001(a), academic teaching hospitals, medical centers, or research institutes affiliated with an institution of higher education.

Clinical Research. Any study, regardless of funding source, involving the evaluation of a diagnostic or therapeutic drug, a vaccine, or a medical device in preparation for a regulatory evaluation or within a regulatory evaluation process, when the protocol requires approval by the Institutional Review Board of the University of South Alabama.

Compensation means anything of economic value, however designated, which is paid, loaned, granted, given, donated, or transferred to any person from any Business Entity for or in consideration of personal services, materials, property, or the like. Compensation does not include:

- a. Salary, royalties, or other remuneration paid by the University to an Investigator or Innovator if the Investigator or Innovator is currently employed by or has an academic appointment at the University;
- b. Payments or the entitlement to payments from the University derived from royalties and fees paid to the University by a third-party for Intellectual Property assigned by an Investigator or Innovator to the University;

- c. Income from investment vehicles, such as mutual funds and retirement accounts, providing the Investigator or Innovator does not directly control the investment decisions made by such vehicles;
- d. Income from seminars, lectures, or teaching engagements sponsored by the University, a federal, state, or local government agency, an Institution of Higher Education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of Higher Education; or
- e. Income from service on advisory committees or review panels for the University, a federal, state, or local government agency, an Institution of Higher Education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of Higher Education.

Conflict of Interest:

Financial Interest. Compensation received from external sources to include the following examples:

- Anything of monetary value including, but not limited to, salary, royalties, or other payments for services, including payments for consulting services and services on advisory committees.
- Intellectual Property Rights including named inventor on a patent/patent assignee, copyrighted material and benefits accruing from such rights.
- Equity interests; e.g., owning or having the right or obligation to acquire stocks or stock options or other securities in a business entity.
- Position in a non-USA entity giving rise to a fiduciary duty such as consultant, employee, director, or any position of management.
- Investigators with funding from the Public Health Service, any sponsored or reimbursed travel (this excludes travel sponsored/reimbursed by government agencies, academic medical centers, public/non-profit institutions of higher education, or their affiliated research institutes).
- Examples of “Financial Interest” do not include compensation received from the University:
- Salary, share in royalties in accordance with University policy, or other remuneration from University of South Alabama (USA).
- Intellectual property rights developed in the course of employment at USA and assigned to USA.

Financial Conflict of Interest. A Financial Conflict of Interest arises when an Employee is in a position to benefit personally from or to influence either directly or indirectly University business, research, or other decisions in ways that could lead to gain for the Employee, the Employee's family, or others. While financial interests should not and, in most cases, do not, compromise intellectual honesty or institutional integrity, under federal law and according to USA policy, they must not have the appearance of compromising the University's values and missions of teaching, research, and public

service. Any financial conflict of interest (real or apparent) should be disclosed so it can be managed, reduced or eliminated in accordance with federal regulations and the terms of this policy.

Significant Financial Interest. Means anything of monetary value that does or could reasonably be perceived to directly and significantly affect the design, conduct, or reporting of funded research, or the performance of other Institutional Responsibilities, whether or not the value is readily ascertainable ¹ For purposes of disclosure, Investigators and Employees must disclose their own financial conflict of interests, as well as their family member's financial conflict of interest.

¹ Note: "Significant" in "Significant Financial Interest" (a term used in the PHS Conflict of Interest Regulations) refers to the potential that the financial interest could affect the design, conduct or reporting of research, not to the dollar value of the financial interest. The University has established a zero dollar threshold for reporting both in dollar value and in percentage of equity holding, meaning that if the financial interest could reasonably be perceived to directly and significantly affect the research it must be reported even if its dollar value or percentages is de minimus.

Conflict Management Plan means a written plan instituted by the University for the management, reduction or elimination of a Financial Conflict of Interest.

Consulting for purposes of this policy, includes but is not limited to the provision of information and expertise on professional matters and the holding of extramural management positions and/or board memberships.

Disclosure Form is the personal financial information provided by an Investigator or Employee which shall include a complete description, including dollar amounts or percentages of ownership, for all Significant Financial Interests related to their professional responsibilities to the University.

Employee means, **for the limited purposes of this Policy**, any individual who is employed by the University, whether full or part time, and includes but is not limited to staff, faculty, postdoctoral fellows, medical house staff, educational trainees and students.

Family Member Family is defined to include spouse, child, grandchild, parent, grandparent, sibling, niece, nephew, aunt, uncle, cousin, in-laws, and step relations in those capacities, as well as any person living in the household of the Employee.

Human Subjects Research is any research that has been designated "human subjects research" by the University's Institutional Review Board.

Institutional Responsibilities means the Investigator's responsibilities associated with his or her Institutional appointment or position, such as research, teaching, and service activities, administration, and institutional, internal and external professional committee service.

Intellectual Property. Intellectual Property Rights are defined as all products of the human intellect that receive legal protection through patent, copyright, trademark or trade secret law developed by Employees that are owned in whole or part by the University, its affiliated foundations according to the University Patent and Invention Policy or by an individual.

Investigator means an individual, regardless of whether or not an Employee of the University as defined in this Policy, who is the project director or the principal Investigator and any other person, regardless of title or position, who is responsible for the design, conduct or reporting of research or scholarly activities conducted in whole or in part under the auspices of the University, which may include for example, collaborators, consultants and/or subaward or subcontract recipients.

Key Personnel: Senior/key personnel are considered to be individuals who have the authority to make independent decisions about the direction of the research and the subsequent conclusions about the results. This does not include administrative personnel or individuals who perform routine, pre-defined, or incidental tasks related to the project. Key personnel must disclose their financial interest to the University. **NOTE:** Staff, postdoctoral fellows who assume independent responsibility for portions of an Investigator's proposed or funded PHS or NSF project are required to meet disclosure requirements of this Policy.

Manage: Taking action to address a financial conflict of interest which can include reducing or eliminating the conflict to ensure that the design, conduct and reporting of research are free from bias. Generally a financial conflict of interest is handled through a Management Plan.

PHS means the Public Health Service of the U.S. Department of Health and Human Services and any PHS awarding components to which authority may be delegated, including without limitation the National Institutes of Health.

PHS-Funded Investigator means an Investigator applying for or participating in any PHS-Funded Research. For the avoidance of doubt, PHS-Funded Investigator includes an Investigator applying for or participating in both PHS-Funded Research and non-PHS-Funded Research.

PHS-Funded Research means any Research or sponsored activity for which funding is available from a PHS awarding component through a grant or cooperative agreement, however authorized, such as a research grant, career development award, center grant, individual fellowship award, infrastructure award, institutional training grant, program project, or research resources award. Notwithstanding the foregoing, PHS-Funded Research does not include any Phase I SBIR Program application or award.

Research means a systematic investigation, study or experiment designed to develop or contribute to generalizable knowledge. The term includes, but is not limited to, basic and applied research (e.g., a published article, book or book chapter) and product development.

University: University is defined to mean all units of the University of South Alabama, including schools, colleges, hospitals, clinics, health system affiliates and any other components not otherwise listed.

4. Policy Guidelines

“Significant” in “Significant Financial Interest” (a term used in the PHS Conflict of Interest Regulations, 42 CFR Part 50) refers to the potential that the financial interest could affect the design, conduct or reporting of research, not to the dollar value of the financial interest.

The University has established a **zero dollar threshold** for reporting in both the dollar value and in percentage of equity holding, meaning that if the financial interest could reasonably be perceived to directly and significantly affect the research it must be reported even if its dollar value or percentages is minimal.

Specifically:

- Investigators and key personnel are responsible for identifying and disclosing actual or potential conflicts covered by this policy. Investigators and/or research personnel should evaluate potential conflicts of interest not only at the outset of their research, but also when a change occurs in their relationship with an outside entity. This may occur at the time a new proposal is submitted, when a new relationship is established with an outside entity, or when a prior relationship with an outside entity changes.
- Investigators and key personnel are responsible for updating their disclosures whenever there is a change to the information contained in the initial disclosure.
- When mandated by a research sponsor (e.g., the Department of Health and Human Services [HHS]), investigators must submit an annual disclosure of financial interests related to their institutional responsibilities (regardless of whether the interest creates a conflict of interest in research), in accordance with the schedule established by the university. The university may also require disclosures at other times. Investigators who are seeking support from HHS must have a current annual disclosure at the time of proposal submission. Investigators with HHS sponsored funding must update their annual disclosures within 30 days of the time they obtain a financial interest with an entity that was not disclosed at the time of the most recent annual disclosure. All changes to financial interests with entities disclosed in the annual disclosure must be updated at the time of the next annual disclosure.

- Investigators are not permitted to begin any research activity when they have reported an actual or apparent conflict of interest before they receive a written determination from the Office of Research Compliance as to how to manage the conflict. Investigators also are not permitted to begin an external activity that would create a conflict of interest relative to an ongoing research activity before they receive a written determination from the Office of Research Compliance as to how to manage the conflict.
- Investigators and key personnel must provide timely and accurate information in response to the Office of Research Compliance and other administrative offices in order for an initial determination regarding the disclosure and/or to monitor their compliance with the management plan.
- Investigators and key personnel must comply with all of the elements of the conflict of interest management plan, as approved by the Office of Research Compliance and the Vice President for Research and Economic Development.
- All investigators must complete training relating to conflicts of interest in research as prescribed by the university.
- Each investigator is responsible for confirming that research personnel under his or her supervision who are involved in proposing, conducting or reporting research on the investigator's project identify and disclose any potential conflict of interest.
- Prohibited conflicts are not acceptable and, therefore, should not occur. Immediate action must be undertaken to eliminate any prohibited conflict.

4.1 Activities Requiring Disclosure

The activities listed under this heading suggest a possibility of conflicting loyalties that can impair objectivity, but disclosure and resulting analysis of relationships may render the activity permissible.

4.1.1 Research and Scholarly Activity

Disclosure is required when an Employee is responsible for the approval, design, conduct, or reporting of sponsored research conducted in whole or in part under the auspices of the University.

4.1.1.1 Employees. Disclosure is required when an Employee or his/her Family Member has a Significant Financial Interest related to research or scholarly activities involving University subordinates or students and the Employee has responsibility for the subordinates' or students' employment and/or academic evaluations.

4.1.1.2 Other individuals. Disclosure is required when a student or postdoctoral scholar or his/her Family Member has a Significant Financial Interest and submits an individual application for fellowship or other research support under the auspices of the University.

For each proposed research activity, Principal Investigators are responsible for determining which faculty, staff, students, and trainees meet the definition of “investigator” defined above. When submitting a grant proposal, named “investigators” are required to submit a Financial Conflict of Interest Certification form and if necessary, a disclosure form.

4.1.2 Human Subjects Research

Disclosure is required to the IRB when an Investigator is responsible for the design, conduct, or reporting of human subject’s research conducted in whole or in part under the auspices of the University.

The disclosure is required of the Principal Investigator, each co-investigator and any other person responsible for designing research, directing research, enrolling research subjects, obtaining subjects’ informed consent, making decisions related to eligibility to participate in research or analyzing or reporting research data.

4.1.3 Consulting

In instances where an employee’s external consulting, with or without compensation, could reasonably pose a conflict of interest, the employee is required to disclose the activity.

4.1.4 Intellectual Property

Disclosure is required prior to the negotiation of any licensing agreements when an Employee is a named inventor on an invention disclosure and the Employee or his/her Family Member has a Significant Financial Interest in a Business Entity related to the Intellectual Property.

4.1.4 Faculty Use of Students in Outside Professional Activities

The University of South Alabama recognizes that the involvement of students in faculty-owned or managed companies or consulting may provide considerable benefit to the student, as long as certain conditions are met.

- Faculty must disclose the proposed involvement of students in their external activities or in company-sponsored research.
- Faculty who anticipate serving as PI or co-PI on sponsored projects and have graduate students or trainees conduct part of the research under their

oversight must develop a conflict of interest management plan addressing protections and ensure activities do not interfere with their academic progress

- Students and postdoctoral trainees should be informed about the source of their funding, the researcher's personal interest and/or involvement with external activities, and if applicable, any agreement concerning copyright, data collection, or patents resulting from the research.

4.1.6 Training and Travel Reporting Requirements for PHS Funded Investigators

Training. Prior to engaging in PHS-Funded Research, and no less often than every four (4) years, all PHS-Funded Investigators must complete training with respect to this Policy and the then-current PHS FCOI rules and regulations. This requirement also applies to any sponsor in addition to PHS that requires training prior to engaging in research.

Travel. PHS-Funded Investigators and other investigators funded by sponsors requiring travel disclosures must disclose the occurrence of any reimbursed or sponsored travel related to their Institutional Responsibilities unless the travel was sponsored or reimbursed by the University.

4.2 Prohibited Activities

The activities cited below involve scenarios that are not generally permissible because they involve potential Financial Conflicts of Interest. Before proceeding with these activities, the Employee must have approval from the appropriate Vice President.

- 4.2.1 Secrecy or confidentiality requirements are not allowed if they impact evaluation of a student, faculty member, or other Employee, or if they delay fulfillment of degree requirements by more than the time contractually allowed for publication and/or protection of intellectual property rights (up to 6 months).
- 4.2.2 Investigators shall not permit a sponsor to compromise the integrity of the scientific analysis or the publication of research results or its conclusions.
- 4.2.3 Evaluation of faculty, staff, postdoctoral fellows, medical house staff, educational trainees or students is not allowed to be based, in whole or in part, on participation in (or refusal to participate in) non-University activities involving Business Entities in which the evaluating Employee or Investigator has a Significant Financial Interest.
- 4.2.4 Individual Investigators or Employees participating in the design, conduct or reporting of a human subjects research study, or their Family Members, shall

not, directly or indirectly, accept any incentives or gifts from a Business Entity that is sponsoring or providing support for the study.

- 4.2.5 Involvement by an Employee in the process of negotiating a license on behalf of the University with a Business Entity in which the Employee or his/her Family Member has a Significant Financial Interest is not allowed.

4.3 Sub-recipient Compliance and Reporting

The University must apply relevant originating sponsor conflict of interest requirements to sub-recipients. Thus, the University must identify whether or not a sub-recipient has a conflict of interest policy compliant with applicable originating sponsor conflict of interest requirements. The Office of Sponsored Projects Administration collects the following at time of proposal submission: See “Sub-recipient Compliance and Reporting” in the *Conflict of Interest in Research Procedures* for additional information.

4.4 Training

Investigators engaged in PHS-funded research (See Appendix 1) are required to complete training regarding their responsibilities under this Policy prior to engaging in any PHS-funded research project and at least every 4 years. In addition, Investigators must complete such training immediately if USA finds that the Investigator is not in compliance with this Policy or a management plan adopted thereunder.

4.5 Confidentiality

Conflict of interest disclosures and determinations concerning conflicts and violations shall be available to:

- 4.5.1 the Investigator or Employee’s University superiors;
- 4.5.2 the appropriate University offices, including but not limited to, the Office of the Vice President for Research, the Office of General Counsel, Internal Audit, Institutional Review Board, Sponsored Projects Administration, Office of Intellectual Property Management, and other Employees whose responsibilities to the University are directly affected by the conflict of interest. In certain circumstances, federal and state law may require public disclosure of information relating to identified conflicts of interest.
- 4.5.3 In other circumstances, including but not limited to conflicts regarding human subject’s research, the University may require public disclosure as part of a conflict management plan.
- 4.5.4 Any information disclosed by an Investigator or Employee as required by this Policy shall be used solely for the purpose of administering this Policy and shall not be used for any other purpose unless required by law. Unauthorized disclosure of any such information by an Employee shall be deemed to be

unethical behavior and shall be punishable under pertinent University Regulations.

4.6 Administrative Actions, Penalties, and Reports of Violations

- 4.6.1 Reports of violations of this policy, such as failure to disclose financial interests, failure to update financial conflict of interests or failure to comply with prescribed management plans, must be reported to the Director, Office of Research Compliance.
- 4.6.2 The Vice President for Research or appropriate Vice President(s) shall investigate all potential non-compliance with this Policy, including potential non-compliance with prescribed management plans. During the investigation, the individual's supervisor will review the report of violation, any response, and any other relevant documentary material.
- 4.6.3 Protection of affected parties is required, to the extent permitted by law and University policies. The University will protect the identity and privacy of those individuals who, in good faith, report apparent non-compliance with this Policy or furnish information regarding such non-compliance. Retaliation of any kind against any individual, who, in good faith, alleges non-compliance or cooperates with the investigation, is prohibited and the retaliator may be subject to discipline under pertinent University policies.

4.7 Appeals

Any decision concerning the existence of a conflict of interest or the appropriateness of a plan to manage, reduce, or eliminate a conflict may be appealed within thirty (30) days to a panel which shall include the Senior Vice President for Academic Affairs or the Vice President for Medical Affairs and the Vice President for Research and Economic Development. The decision of the panel shall be final.

4.8 Institutional Reporting and Record Retention

The Office of Research Compliance shall be responsible for maintenance of all records that meet the requirements of 42 CFR Part 50 Subpart F:

- 4.8.1 All disclosures and management plans and related information must be retained for a minimum of three years from the date of the final expenditure report on a grant or contract or three years from the date of project completion when no final expenditure report is required.

4.8.2 All other dates specifies in 45 CFR 74.52(b) and 92.42(b) when applicable for federal funds.

4.9 Public Accessibility

This policy and each update of this policy will be publicly accessible on the University of South Alabama's website. Additionally, the Institution will make available by written response to any requestor within five business days information regarding specified financial conflict of interest related to PHS funded research. Disclosed information will be provided to the extent required by applicable PHS regulations and state law.

4.10 Retrospective Review and Reporting

In cases where a financial conflict of interest is not identified or managed in a timely manner, retrospective review and reporting is required for PHS-funded research or Non-PHS organizations that require compliance with PHS Financial Conflict of Interest Regulations (See Appendix 1)

The institution has 60 days to determine if a conflict of interest exists and implement a management plan if needed. Additionally, if a conflict of interest is identified as it was not managed due to noncompliance by the Investigator, the Institution has 120 days from the date of noncompliance was identified to conduct a retrospective review of the Investigator's activities and the research project to assess if any bias in the design, conduct, or reporting of the research as a result.

5. Procedures

The *Conflict of Interest in Research Procedures* must be followed to ensure compliance with this policy. The Procedures supplement this Policy and apply to all sponsored research subject to Public Health Service and National Science Foundation regulations, and other research activities involving potential conflict of interest.

6. Enforcement

For violations of this Policy, one or more of the following restrictions may include, but not limited to:

- Freeze research funds, or otherwise suspend, a project or projects related to the policy violation;
- Remove the individual found to be in violation from a role as Principal Investigator or Investigator on a project or projects related to the policy violation;
- Prohibit submission of new applications to the Institutional Review Board and/or Sponsored Projects Administration until resolution of the relevant conflict of interest issues or for a specified period of time;
- Notification to funding agencies and/or professional journals;

- Letter of reprimand; and/or
- Reassignment of duties

The individual Investigator or Employee may appeal the restriction(s) to a panel which shall include the Senior Vice President for Academic Affairs, the Vice President for Medical Affairs, and the Vice President for Research and Economic Development. The decision of the panel shall be final.

In situations involving the health or safety of any person or the potential loss of significant University resources, the panel may implement any restrictions that are necessary to protect these persons and resources pending the outcome of the investigation. Otherwise, no restrictions, disciplinary or administrative action shall occur until the conclusion of the violation evaluation process set forth in this Policy.

7. Related Documents

USA Related Documents:

Conflict of Interest in Research Procedures

Conflict of Interest and Conflict of Commitment Policy

External Professional Activities Policy

[Financial Conflict of Interest Disclosure Form](#)

[Guidance for Determining if a Financial Conflict of Interest is Related to PHS-Funded Project](#)

[PHS Subrecipient instructions and disclosure forms](#)

[Notification letter informing students/staff of potential conflict of interest](#)

Related Regulations:

2011 Public Health Service (PHS) Regulations: Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is Sought ([42 C.F.R. Part 50, Subpart F](#))

[2005 National Science Foundation: Chapter V: Grantee Standards](#)

APPENDIX 1

PHS Organizations

Organizations That Require Compliance With PHS Financial Conflict Of Interest Regulations

U.S. Public Health Services Agencies include:

- Agency for Healthcare Research and Quality (AHRQ)
- Agency for Toxic Substances and Disease Registry
- Centers for Disease Control (CDC)
- Food and Drug Administration (FDA)
- Health Resources and Services Administration (HRSA)
- Indian Health Services (IHS)
- National Institutes of Health (NIH)
- Office of Global Affairs
- Office of the Assistant Secretary for Health
- Office of the Assistant Secretary for Preparedness and Response
- Substance Abuse and Mental Health Services Administration (SAMHSA)

This list of PHS agencies is taken from the U.S. DHHS Organizational Chart at: www.hhs.gov/about/orgchart Because there may be changes, if the agency you are interested in is not on this list and you are unsure if it is a PHS agency, check with the Sponsored Projects Administration.

Non-PHS Organizations Which Have Adopted the PHS Regulations:

- Alpha-1 Foundation
- Alliance for Lupus Research
- American Asthma Foundations
- American Cancer Society
- American Heart Association
- American Lung Association
- Arthritis Foundation
- CurePSP
- Juvenile Diabetes Research Foundation
- Lupus Foundation of America
- Patient-Centered Outcomes Research Institute
- Susan G. Komen for the Cure