UNIVERSITY OF SOUTH ALABAMA

Responsible Office: Office of Research Compliance and Assurance

Last Review Date: 7/15/2020

Next Required Review: 7/15/2025

Conflict of Interest in Research Procedures

1.0 Purpose

These procedures supplement the University *Conflict of Interest in Research Policy*. The policy and associated procedures are derived from the Final Rules promulgated by Public Health Service (PHS) Financial Conflict of Interest on Objectivity in Research, and the National Science Foundation Conflict of Interest regulations.

They are intended to provide transparent processes for disclosure, review, and management of conflict of interest within the University research community. The Procedures define the Institutional requirements to Manage, Reduce or Eliminate potential financial Conflicts of Interest.

2.0 Applicability

All sponsored research programs and research related activities at the University of South Alabama.

3.0 Definitions

Terms used herein are as defined in the *USA Conflict of Interest in Research Policy*

4.0 Policy

The Conflict of Interest in Research Policy requires conflict of interest disclosures by Investigators via the COI Risk Manager online system prior to engaging in any PHS funded or Non-PHS compliant organizations activities described in section 5.0 below. The Investigator must provide complete and accurate information about all potential Financial Interests that reasonably appear related to his/her professional responsibilities to the University.

The Investigator will not engage in any activities involving a potential financial conflict of interest until the Designated Official determines whether a Financial Interest creates a financial conflict of interest and approves a plan to manage, reduce or eliminate any

such conflicts. The University has established a **zero dollar** threshold for reporting both in dollar value and percentage of equity holding meaning that if the financial interest could reasonably be perceived to directly and significantly affect the research is must be disclosed.

5.0 Procedures

The following responsibilities for disclosure, review and management of conflict of interests in research resides with the following individuals:

Conflict of Interest Management Team Member

Management team members are non-conflicted faculty peer and/or administrative staff appointed by the designated official to review pertinent documentation, proposed management plans, and reports and to make recommendations to the Designated Official regarding Investigator and other employee compliance with the Conflict of Interest Policy. Each team will consist of three members and recommend conditions/restrictions, if any, to consider in the management of a potential or actual financial conflict of interest.

Designated Official

The Designated Official, for purposes of these policies and procedures, is the Executive Director, Office of Research Compliance and Assurance and is responsible for supporting the Vice President for Research and Economic Development in implementing this policy and procedures. The Designated Official shall review disclosure forms from Investigators and assist in the development of Management Plans that specify the actions taken to manage the financial conflict of interest. The Designated Official works closely with conflict of interest management team members.

Office of Research Compliance and Assurance

The Office of Research Compliance and Assurance is available to provide advice and assistance to any individual on the interpretation of these requirements and the applicability to a specific situation.

Investigator

The Investigator is responsible for reporting of financial conflict of interests as outlined in these procedures, compliance with Management Plans, and submission of any Publications that require disclosure of an interest per a Management Plan.

Vice-President for Research and Economic Development

The Vice-President for Research appoints the Designated Official and serves as the final arbiter in the appeals process. The Vice President and Designated Official shall make the determination regarding whether or not an Employee's real or potential Financial Conflict of Interest must be managed, reduced or eliminated.

Activities that warrant a reduction or elimination of a Conflict of Interest will be reviewed by the Designated Official and the Institutional Official (Vice President for Research and Economic Development) and a determination made. If Activities require reduction or elimination, a plan for doing so will be developed by the Designated Official and the Investigator.

5.1 What Must Be Disclosed

Investigators are encouraged to disclose any situation that could conceivably be viewed as a conflict of interest or a reportable financial interest. Please also refer to the USA Conflict of Interest in Research Policy for activities requiring disclosure include, but not limited to:

5.1.1 Ownership interest in any entity providing funds for research activities

5.1.2 Ownership interest in any entity that owns intellectual property that could reasonably be affected by research activities

5.1.3 Financial interest that could reasonably appear to be related to your institutional responsibilities (including your spouse and dependent children)

5.1.4 Serving on a board of directors or scientific advisory board of a business that provides financial support for University research conducted by the Investigator/Employee or a family member.

5.1.5 Serving in an executive position in a for-profit or not-for-profit business which conducts research or other activities in an area related to your University duties.

5.1.6 Serve as a paid/unpaid consultant for any entity providing funds for research activities

5.1.7 Assignment of students or trainees to University research projects sponsored by a business which you or a family member has a financial interest

5.1.8 Participating in University research, clinical trials, or service agreements which are funded by a grant or contract from a business which the Investigator/Employee of family members has a financial interest

Financial Interests do **NOT** include:

(1) Salary, royalties or other remuneration paid by University of South Alabama to the Investigator if the Investigator is currently employed or otherwise appointed by the University;
(2) Intellectual property rights assigned to University of South Alabama and agreements to share in royalties related to such rights;
(3) Equity interests through investment vehicles, such as mutual funds and retirement accounts, as long as the Investigator does not directly control the investment decisions made in these vehicles;
(4) Income from seminars, lectures or teaching engagements sponsored by a federal, state or local government agency, a qualifying institution of higher education, an academic teaching hospital, a medical center or a research institute that is affiliated with a qualifying institution of higher education;
(5) Income from service on advisory committees or review panels for a federal, state or local government agency, a qualifying institution of higher education, an academic teaching hospital, a medical center or a research institute that is affiliated with a qualifying institution of higher education; or
(6) Sponsored or reimbursed travel sponsored or paid by a federal, state or local government agency, a qualifying institution of higher education, an academic teaching hospital, a medical center or a research institute that is affiliated with a qualifying institution of higher education.

5.2 To Whom Must a Disclosure be Made?

Disclosures will be routed to the Office of Research Compliance and Assurance. The Executive Director will make the determination, in conjunction with the Vice President for Research and Economic Development if needed, whether or not a potential or actual conflict will require action on the part of the University to manage, reduce or eliminate the conflict.

5.2.1 PHS Agencies and Specified Non-PHS Agencies

Investigators submitting proposals to a PHS agency or Non-PHS organizations that require compliance with PHS Financial Conflict of Interest Regulations must disclose actual or potential conflicts of interests:

- At the time of proposal submission
    - Investigators must certify that appropriate disclosures have been made at the time of proposal submission. For all PHS proposals and Non-PHS organizations that adhere to PHS Financial Conflict of Interest regulations, the *Conflicts of*

Interest Certification form must be completed by the Principal Investigator. This form is submitted with the grant proposal via Sponsored Projects Administration online management system, Cayuse. The *Conflicts of Interest Certification* form shall be updated by the Principal Investigator any time additional individuals are identified at the time of proposal award or thereafter. The *Conflict of Interest Certification* form must be subsequently updated.

- Annually during the period of award for PHS-funded research or Non-PHS organizations. This requirement applies to the Investigator and key personnel listed on the Conflicts of Interest Certification form.

- Within 30 days of acquiring, or discovering a new financial conflict of interest

- As required by the sponsor or by specific terms of and award.

5.2.2 Other Funding Avenues

The *Conflict of Interest Disclosure* form available via the COI Risk Manager online system must be completed or updated prior to:

- Initiating a technology licensing agreement
- Creation of new startup company
- External supported activities for University programs, projects, activities and services
- Financial Interest that is related to his/her professional responsibilities to the University

5.2.3 Disclosure to Students

Prior to retaining students or trainees on research projects that may involve a potential or actual conflict of interest; the Investigator must provide written notification to the student, of any interests in outside companies that may be perceived to benefit from the student's research. Student involvement in Faculty company activities may provide the potential for substantial benefits to the education and career development of the student. Such involvements need to be guided to avoid conflicts of interest or interference with the student's primary educational and research duties.

The Investigator's written notification must be acknowledged by the student or trainee. Additionally, faculty must discuss conflict of interest principles intended to guide productive engagement of students in faculty enterprises. A sample letter of notification is available on the Conflict of Interest website.

5.2.4 Travel Disclosure

PHS-Funded Investigators or organizations that require compliance with PHS Financial Conflict of Interest Regulations must disclose the occurrence of any reimbursed or sponsored travel related to their Institutional Responsibilities paid for by a third-party entity, including non-profit organizations. Disclosure is *not* required for travel sponsored by or reimbursed by a government agency, a U.S. Institution of higher education or a research institute affiliated with such, a U.S. medical center, or a U.S. academic teaching hospital.

When a travel request submitted through Concur indicates that an employee's travel is sponsored or reimbursed by a third party and the traveler is a PHS-funded Investigator, the Office of Research Compliance will receive an automated notification to review the Travel Request. *This does not slow down the approval process, as the Office of Research Compliance is not involved in approving the Travel Request.* The Office will notify the traveler if further disclosure of the travel and reimbursement information is required, including a determination or disclosure of monetary value, in order to determine whether the travel constitutes a financial conflict of interest with PHS-funded research.

5.3 Training

5.3.1 Identifying Who Needs Training

The University's Office of Sponsored Projects Administration Internal Processing Form completed for transmission of grant applications, contracts or cooperative agreements, specifies within the Conflict of Interest section, if the submission is to Public Health Service (PHS) agency or Non-PHS Conflict of Interest compliant agency. If so, a link is provided to further instruct completion of the *Financial Conflicts of Interest Certification* form.

Each Investigator and Key Personnel listed on the *Financial Conflicts of Interest Certification* form **must** complete the University's Conflict of

Interest training requirement if the proposal is funded.

5.3.2 How Do I Complete Training?

- The Collaborative Institutional Training Initiative (CITI) online program is a nationally-recognized source for research-related training. The Office of Research Compliance and Assurance utilizes CITI training to meet PHS agencies and other applicable granting agencies/foundation training requirements.
- Instructions for accessing the CITI training program are located on the Conflict of Interest website.

5.3.3. When Must Training Be Completed?

Each Investigator and key personnel must complete the University's COI training:

- Prior to engaging in research related to PHS or Non-PHS conflict of interest complaint agency
- At least every four years, and
- Immediately following:
    - University COI policies change in a manner that affects Investigator requirements;
    - University finds an Investigator is noncompliant with Institution's policy or Management Plan.

5.3.4 Verification of Training

The *Financial Conflict of Interest Certification* form must be uploaded in the Office of Sponsored Projects Administration online system, Cayuse. Prior to or at the time of grant award, the Office of Research Compliance and Assurance will upload COI training certificate(s) in Cayuse with the affiliated grant proposal.

The Office of Grants and Contracts Accounting will validate required training prior to issuing a grant account/fund number. To prevent possible delays in establishment of grant account/fund number, it is recommended that COI training be initiated upon receipt of a priority score and anticipate a fundable score. The Office of Research Compliance and Assurance receives an automated email notification upon completion of training.

5.4 Review, Management & Monitoring Conflicts of Interests

5.4.1 Identifying Financial Conflict of Interest

The Designated Official (Office of Research Compliance and Assurance) reviews conflict of interest disclosure forms for completeness and communicates with Investigators as necessary to obtain all required information. A preliminary review is conducted to determine whether a financial conflict of interest exists. This is exercised in cooperation with the relevant research department/unit and participation by the Investigator. A variety of criteria may be considered in determining whether a specific financial interest creates a conflict of interest with respect to a PHS funded project.

The review will consider the nature of the research, the degree to which the conflict is related to the research, the extent to which the interest could be affected by the research, and any management strategies that would mitigate, reduce, or eliminate the conflict. Management strategies may include, but not restricted to:

- Modification of the research plan
- Public disclosure of financial conflicts of interest
- Disclosure to human subject participants
- Change of personnel or personnel responsibilities
- Reduction or elimination of financial interest (sale of an equity interest)
- Appointment of an independent monitor capable of taking measures to protect the design, conduct and reporting of research against bias or appearance of bias
- Severance of relationships

Based on the preliminary review, the following may occur; 1) no further action recommended or 2) action requires clarification or 3) development of a management plan.

If a management plan is warranted, the investigator will be advised on how the project must be managed and other actions that must be taken to eliminate or reduce the conflict. This is communicated to the Investigator in the form of a Management Plan.

5.4.2 Management Plan

If it is determined that a financial interest is related to PHS-funded research, Non-PHS compliant agency or an external faculty enterprise, a management plan may be required to eliminate or manage the financial and/or personal conflict of interest, as appropriate. The following will occur:

- Office of Research Compliance and Assurance works in conjunction with Investigator(s) and/or Departmental Supervisor to develop draft management plan for any such conflicts before awarded funds are expended.
- Office of Research Compliance and Assurance appoints management team members
- Management team members review and discuss prior to approval of management plan
- Management plans are approved and signed by the Investigator, Department Chair/Supervisor and Vice President for Research and Economic Development

The Investigator may not initiate research that gives rise to Financial Conflict of Interest, or the appearance of, until the review and approval process is complete.

5.4.3 Conflict of Interest Management Team

The management team reviews Investigator reports, as prescribed in the management plan.

An initial meeting with the Investigator may be initiated at the request of the Management Team. For example, if there are concerns regarding Investigator's interactions with an external Entity, influence on the Investigator's university activities, and/or compliance with terms of the Management Plan. Additionally, the Office of Research Compliance and Assurance may participate in the monitoring process or initiate an exit interview, if prescribed in the management plan.

The Management team will meet at least annually to review the Management Plan and required reporting including:

- Awards received –both grants and contracts and gifts
- Publications and abstracts submitted and published

- A list of relevant research projects being pursued
- Change in status if the individual is invested in a related startup company

5.5 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:

- *Documentation of Subrecipient: Financial Conflicts of Interest Policy Commitment Form* (See Link to Form 1)
- Additionally, if sub-recipient follows the University's Conflict of Interest Policy, sub-recipient completes *Subreceipient Disclosure of Financial Interest in Research* (See Link to Form 2)

If the University carries out the PHS-funded research through a sub-recipient, the University will incorporate as part of a written agreement with the sub-recipient terms that establish whether the University's or the sub-recipient's policy on conflict of interest in research will apply to the sub-recipient Investigators.

If the sub-recipient's policy will apply, the sub-recipient will certify as part of the agreement that its policy complies with the PHS regulations. Additionally, the agreement shall specify time period(s) for the sub-recipient to report all identified financial conflicts of interest to the University to enable the University to provide timely reports to PHS.

Alternatively, if the University's policy on conflict of interest will apply, the agreement shall specify time period(s) for the sub-recipient to submit all sub-recipient Investigator disclosures of financial interests to the University. Such time periods shall be sufficient to enable the University to comply with timely review, management, and reporting obligations under the PHS regulations prior to expenditure of funds or within 60 days of any subsequently identified financial conflict of interests.

5.6 Retrospective Review and Reporting

The following procedures are applicable to **PHS-funded research** or **Non-PHS organizations** that require compliance with PHS Financial Conflict of Interest Regulations.

5.6.1 The University must, within 120 days of its determination of noncompliance, complete a retrospective review of the Investigator's activities and the PHS-funded research to determine whether the design, conduct, or reporting of the PHS-funded research, or any portion thereof, conducted during the period of noncompliance, was biased. Retrospective reviews will be conducted by the Office of Research Compliance and Assurance, in collaboration with the Vice President for Research and Economic Development to determine if the research or any part of it was biased, to include a mitigation plan to address any issues.

5.6.2 The University is required to document the retrospective review and report detailed findings to PHS, including at least the following key elements:

- project number;
- project title;
- Principal Investigator or contact Principal Investigator if there are multiple Principal Investigators on the project;
- name of the Investigator with the Financial Conflict of Interest;
- name of the Entity with which the Investigator has a Financial Conflict of Interest;
- reason(s) for the retrospective review;
- detailed methodology used for the retrospective review (e.g., methodology of the review process, composition of the review panel, documents reviewed);
- findings of the review; and
- conclusions of the review.

5.6.3 Based on the results of the retrospective review, USA will update the previously submitted Financial Conflict of Interest report, if appropriate, specifying actions that will be taken. If bias is found, USA must notify PHS promptly and submit a mitigation report, to include:

- elements documented in the retrospective review;
- a description of the impact of the bias on the research; and
- USA's plan of action or the actions taken to eliminate or mitigate the effect of the bias

5.6.4 Thereafter, the Institution will submit financial conflict of interest reports annually as prescribed by PHS COI regulation.

6.0 Enforcement

The responsible parties for oversight and enforcement are:

Policy Oversight:	Office of Research Compliance and Assurance
Policy Enforcement:	Vice President for Research and Economic Development

7.0 Related Documents

Conflict of Interest and Conflict of Commitment Policy
Guidance for Determining if a Financial Conflict of Interest is Related to PHS-Funded Project
PHS Agencies and Non-PHS organizations that require compliance with PHS COI Regulations
PHS Subreceipient instructions and disclosure forms
Notification Letter Informing Students/Staff of Potential Conflict of Interest

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)

Organizations That Require Compliance With PHS Financial Conflict Of Interest Regulations

PHS Organizations:

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
- Alzheimer's Drug Discovery 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