



I. TITLE:

Financial Conflict of Interest (FCOI) Policy Governing Sponsored Programs

II. POLICY STATEMENT:

Research is one component of our mission at Alabama State University (ASU) to enhance the quality of life through innovative discovery. To prevent subjectivity and bias in the substantial research conducted at the University, it is necessary that we develop a policy that complies with federal government regulations. The sponsorship received from external agencies can lead to the development of conflicting relationships between the University and external sponsor(s) who fund specific programs. This policy will minimize the potential risks associated with financial conflict of Interest of faculty, staff, and students.

III. SCOPE OF POLICY:

This policy applies to all investigators who endeavor to receive allocations from grant funding agencies; additionally, it ensures that immediate family members are not affected by the research being conducted or the proposed funded educational activity.

IV. EFFECTIVE DATE:

Immediately upon approval by the ASU Board of Trustees.

V. AUDIENCE:

All investigators involved in sponsored programs are expected to have knowledge and understanding of the FCOI Policy Governing Sponsored Programs.

VI. DESIGNATED RESPONSIBILITIES AND APPLICABILITY OF POLICY:

Alabama State University and the appointed University officials are responsible for the oversight and administration of the FCOI Policy.

Office of Research and Sponsored Programs

- a. Requires all PI's and Co-PIs to complete FCOI trainings.
- b. Responsible for informing investigators of the FCOI policy, federal regulations, and disclosures.

Institutional Designee

- a. Reviews disclosures of Statements of Financial Interest (SFI) from each investigator that endeavors to engage in a Public Health Service funded or other sponsored activity.
- b. Responsible for collecting and maintaining oversight of submitted SFI disclosure forms related to the following:
 - i. Conducting and reporting of sponsored activities

- ii. Federal compliance in research
- iii. Management and mitigation of potential conflicts generating from SFI disclosures

VII. POLICY MANAGEMENT

Responsible Office(s): Office of Research and Sponsored Programs

Responsible Executive: Business and Finance

Responsible Officer(s): Institutional Designee

VIII. DEFINITIONS:¹

- **Financial Conflict of Interest (FCOI)** - significant financial interest that has a direct and significant effect on the design, conduct, or reporting of funded programs.
- **Financial Interest** - anything of monetary value, whether or not the value is readily ascertainable.
- **Immediate Family** - (1) a spouse or domestic partner; (2) any person used for the purposes of determining tax liability (dependent child, stepchild, or other dependents) throughout the period covered by the disclosure statement; (3) A related or non-related, unmarried adult who resides in the same household as the covered individual and with whom the covered individual is financially interdependent as evidence, for example, by the maintenance of a joint bank account, mortgage, or investments.²
- **Investigator** - a principal investigator, project director, co-principal investigator, collaborator, consultant, or any other persons responsible for the design, conduct, or reporting of research at the University.
- **Public Health Service (PHS)** means the Public Health Service of the U.S. Department of Health and Human Services, and any components of the PHS to which the authority of the PHS may be delegated. The components of the PHS include, but are not limited to, the Administration for Children and Families, Administration on Aging, Agency for Healthcare Research and Quality, Agency for Toxic Substances and Disease Registry, Centers for Disease Control and Prevention, Federal Occupational Health, Food and Drug Administration, Health Resources and Services Administration, Indian Health Service, National Institutes of Health, and Substance Abuse and Mental Health Services Administration.
- **Research** - a systematic investigation, study or experiment designed to develop or contribute to generalizable knowledge.
- **Significant Financial Interest (SFI)** - anything of monetary value, including but not limited to, salary or other payments for services (e.g., consulting fees or honoraria); equity interests (e.g., stocks, stock options or other ownership interests); and intellectual property rights (e.g., patents, copyrights and royalties from such rights).

¹ Code of Federal Regulations. (2000) Title 42, Vol. 1, parts 1-399, cite 42CFR50

² University of Texas, & Multimedia Services. (2019). 1.33 Conflict of Interest, Conflict of Commitment, and Outside Activities. Retrieved from <https://www.utsa.edu/hop/chapter1/1-33.html>.

IX. PROCEDURES:

ASU will ensure continued compliance with the Alabama code of ethics for public officials and employees. (Code of Alabama 1975, Title 36, Chapter 25) and the Code of Federal Regulations (42 CFR 50, subpart F; 45 CFR 94); additionally, any FCOI regulations concerning grant funding agencies. Investigators must participate in any ongoing Research training through the University. Principal Investigators, Project Director, or Co-Principal Investigator must take the following steps before submitting a research proposal:

- (1) Complete all research, ethics, and compliance trainings required by the University before pursuing any grant funding.

TRAINING

Each Investigator must complete online training on this Policy, the Investigator's responsibilities regarding disclosure and the PHS regulations. This training must be completed prior to engaging in research funded by PHS and at least every *four* years thereafter. Each Investigator must also complete training within a reasonable period of time as determined by the Institutional Designee in the event that this Policy is substantively amended in a manner that affects the requirements of Investigators, if the Investigator is new to the institution, or if it is determined that the Investigator has not complied with this policy or with a management plan related to their activities. Alabama State University utilizes CITI training as the main training source to educate Investigators and related staff on FCOI.

- a. Certification must be provided to the Office of Research and Sponsored Programs (ORSP) verifying successful completion.
- (2) Complete a FCOI Disclosure Form within thirty days of submitting a proposal.

DISCLOSURE OF FINANCIAL INTERESTS

All Investigators are required to disclose their outside financial interests as defined above to the Institution on an annual and on an ad hoc basis, as described below. The Institutional Official is responsible for the distribution, receipt, processing, review and retention of disclosure forms. When appropriate, the COI Committee will assist with the review of those forms and processes.

a) Annual Disclosures

All Investigators must disclose their Significant Financial Interests that are related to the Investigator's institutional responsibilities to the Institution, through the Institutional Designee, on an annual basis. All forms should be submitted to the Institutional Designee.

b) Ad Hoc Disclosures

In addition to annual disclosure, certain situations require ad hoc disclosure. All Investigators must disclose their Significant Financial Interests to the Institution, through the Institutional Designee, within 30 days of their initial appointment or employment.

Prior to entering into Public Health Services (PHS) or other sponsored projects or applications for PHS or other sponsored projects, where the Investigator has a Significant Financial Interest, the Investigator must affirm the accuracy of the annual disclosure or submit to the Institutional Designee an ad hoc updated disclosure of his or her Significant Financial Interests with the outside entity. The Institution will not submit a research proposal unless the Investigator(s) have submitted such ad hoc disclosures.

In addition, all Investigators must submit to the Institutional Designee an ad hoc disclosure of any Significant Financial Interest they *acquire* or *discover* during the course of the year within thirty (30) days of discovering or acquiring the Significant Financial Interest.

c) Travel

Investigators must also disclose reimbursed or sponsored travel related to their institutional/ external responsibilities, as defined above in the definition of Significant Financial Interest. Such disclosures must include, at a minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination, the duration, and, if known, the monetary value. The Institutional Designee will determine if additional information is needed (e.g., the monetary value if not already disclosed) to determine whether the travel constitutes a Financial Conflict of Interest with the Investigator's research. **All forms must be submitted to the Institutional Designee.**

- a. This form must be completed each time an investigator submits a proposal to different funding agencies.
- b. This must also be completed annually to remain in compliance with the federal regulations regarding FCOI.

REVIEW OF FCOI BY THE INSTITUTIONAL DESIGNEE

If the submitted disclosure form reveals a Significant Financial Interest, it will be reviewed promptly by the Institutional Designee or designee for a determination of whether it constitutes a Financial Conflict of Interest. If a Financial Conflict of Interest exists, the Institutional Designee will take action to manage the financial conflict of interest including the reduction or elimination of the conflict, as appropriate. Under special considerations, the Institutional Designee may consult the COI Committee for guidance in specific cases or in the application of the policy to a particular situation defined by ASU.

A Financial Conflict of Interest will exist when the Institutional Designee determines that a Significant Financial Interest could directly and significantly affect the design, conduct, or reporting of PHS-sponsored and non-PHS sponsored research. If the Institutional Designee determines that there is a Financial Conflict of Interest that can be managed, he or she must develop and implement a written management plan. The affected Investigator must formally agree to the proposed management strategies and sign the written management plan before any related PHS/other-sponsored research goes forward.

The Institutional Designee will periodically review the ongoing activity, monitor the conduct of the activity (including use of students and postdoctoral appointees), to ensure open and timely dissemination of the research results, and to otherwise oversee compliance with the management plan.

a) Retrospective Review

In addition, if the Institutional Designee determines that a Financial Conflict of Interest was not identified or managed in a timely manner, including but not limited to an Investigator's failure to disclose a Significant Financial Interest that is determined to be a Financial Conflict of Interest, or failure by an Investigator to materially comply with a management plan for a Financial Conflict of Interest, an COI committee appointed by the Institutional Designee will complete a retrospective review of the Investigator's activities and the PHS-sponsored research project to determine whether the research conducted during the period of non-compliance was biased in the design, conduct or reporting of the research.

Documentation of the retrospective review shall include the project title, PI, name of Investigator with the Financial Conflict of Interest, name of the entity with which the Investigator has the Financial Conflict of Interest, reason(s) for the retrospective review, detailed methodology used for the retrospective review, and findings and conclusions of the review.

The Institutional Designee will update any previously submitted report to the PHS/other agency or the prime PHS/other-awardee relating to the research, specifying the actions that will be taken to manage the Financial Conflict of Interest going forward. This retrospective review will be completed in the manner and within the time frame established in PHS/other regulations. If bias is found, the institution will promptly notify the PHS/other Awarding Component and submit a mitigation report in accordance with the PHS/other regulations. The mitigation report will identify elements documented in the retrospective review, a description of the impact of the bias on the research project and the plan of action to eliminate or mitigate the effect of the bias.

- (3) Complete the required clearance forms upon approval of steps (1) and (2).
 - a. Request forms from ORSP.
 - b. Write proposal and attach it to clearance form and a copy of Request for Proposal (RFP).

- c. Approval from Chair and Dean or Director and Vice President, respectively.
- d. Submit all documents to ORSP for processing.

The ORSP will notify all investigators of successfully approved submissions.

CORRECTIVE ACTION

If it has been determined that the Institution has identified a Significant Financial Interest (SFI) that was not disclosed, identified, reviewed or managed in a timely manner, the designated official(s) shall within 60 days: review and make the determination of an FCOI and report the FCOI, if it exists, to the PHS/NIH or other relevant agency.

REPORTING RESULTS OF A NON-COMPLIANCE REVIEW

If an FCOI exists, ORSP will conduct a retrospective review within 120 days of the Institution's determination of noncompliance, properly document the incident, and implement a management plan that shall specify the actions that have been and will be taken to manage the FCOI going forward.

REPORTING TO PHS

The Institutional Designee will report all financial conflicts of interest or non-compliance to PHS in accordance with PHS regulations.

PUBLIC ACCESSIBILITY

Prior to the expenditure of funds, the Institution will publish on the ORSP webpage or respond to any requestor within five business days of the request, information concerning any Significant Financial Interest that meets the following criteria:

- a) The Significant Financial Interest was disclosed and is still held by the senior and key personnel;
- b) A determination has been made that the Significant Financial Interest is related to the PHS-funded or other sponsored research; and
- c) A determination has been made that the Significant Financial Interest is a Financial Conflict of Interest.

The information to be made available shall be consistent with the requirements of the PHS and/or agency regulations.

REGULATORY AUTHORITY

This policy implements the requirements of 42 CFR 50 Subpart F and 45 CFR 94; where there are substantive differences between this policy and the requirements, the requirements shall take precedence.

II. REFERENCES

NIH: NIH Financial Conflict of Interest Regulation

NSF: NSF Grantee Standards

42 CFR 50, subpart f

Document History

Approved by BOT: September 18, 2020