**The University of West Alabama**

**Financial Conflict of Interest Policy and Procedures for**

 **Research and Related Activities**

**Introduction**

The University of West Alabama (UWA) has adopted this Financial Conflict of Interest Policy and Procedures for Research and Related Activities (FCOI Policy) to ensure that faculty and staff are informed about potential conflicts, diligently disclose their financial interests internally, and that any identified conflicts are carefully reviewed and managed. The purpose of the FCOI Policy is to:

* implement requirements of the federal regulations as set forth by the Public Health Service (PHS) 42 CFR Part 50 and the National Science Foundation (NSF) Proposal & Award Policies & Procedures Guide (PAPPG) that govern UWA and each Investigator’s responsibilities for promoting objectivity in federally funded research.
* publish and disseminate standards that provide a reasonable expectation that

the design, conduct, and reporting of research under NSF-funded grants, PHS-funded grants, subgrants, or cooperative agreements will be free from bias resulting from Investigator financial conflicts of interest.

**Definitions**

Compliance and Research Officer (CRO): UWA employee who ensures that research activities adhere to all relevant laws, regulations, and institutional policies.

Designated Institutional Official (DIO): the administrator designated by UWA to review disclosures of Significant Financial Interest of the Investigator (and those of the Investigator’s spouse and dependent children) related to an Investigator’s Institutional Responsibilities.

Disclosure Form: initially submitted prior to proposal submission and is updated during the period of an award either on an annual basis or as new reportable Significant Financial Interests are obtained.

Entity: any domestic or foreign, public or non-public (private) organization from which a UWA employee (and his/her immediate family) receives renumeration or in which they have an ownership or equity interest.

Financial Conflict of Interest (FCOI): a Significant Financial Interest that could directly and significantly affect the design, conduct, or reporting of federally funded research.

Institutional Responsibilities:an Investigator's professional responsibilities on behalf of UWA, and as defined in this policy, which may include the following activities: research, research consultation, teaching, professional practice, institutional committee memberships, and service on committees such as the Institutional Review Board, Institutional Animal Care and Use Committee, Data Integrity Committee, or any other relevant institutional committees.

Investigator:the Project Director (PD), Principal Investigator (PI), and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of federally funded research, or proposed for such funding, which may include, for example, collaborators or consultants.

Research*:*a systematic investigation, study, or experiment designed to develop or contribute to generalizable knowledge. The term encompasses basic and applied research and product development.

Retrospective Report – a report from the CRO to the DIO or agency which may be required when bias is found during a Retrospective Review.

Retrospective Review – a compliance review conducted by the CRO of a FCOI that was not identified or managed in a timely manner.

Senior/Key Personnel: individuals designated by UWA as essential to the grant project, including the Investigator and any other persons identified as such in grant applications or reports.

Significant Financial Interest (SFI or SFIs): a financial interest consisting of one or more of the following interests of the Investigator (and those of the Investigator's spouse and dependent children) that reasonably appears to be related to the Investigator's Institutional Responsibilities: (1) With regard to any publicly traded entity, a SFIexists if the value of any remuneration received from the entity in the twelve months preceding the disclosure and the value of any equity interest in the entity as of the date of disclosure, when aggregated, exceeds $5,000. For purposes of this definition, remuneration includes salary and any payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorship); equity interest includes any stock, stock option, or other ownership interest, as determined through reference to public prices or other reasonable measures of fair market value; (2) With regard to any non-publicly traded entity, a SFIexists if the value of any remuneration received from the entity in the twelve months preceding the disclosure, when aggregated, exceeds $5,000, or when the Investigator (or the Investigator's spouse or dependent children) holds any equity interest (e.g., stock, stock option, or other ownership interest); or (3) Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests. “Financial interest” does not include, for example, interests of any amount in diversified financial holdings, or royalties or other remuneration paid by UWA.

**Procedures**

Investigators are required to complete FCOI training for PHS-funded grants. Training includes informing Investigators on UWA’s FCOI Policy, the Investigator’s responsibilities regarding disclosure of SFIs, and federal regulations. FCOI training should occur every four years, and immediately when any of the following circumstances apply: (1) UWA revises its FCOI Policy in any manner that affects Investigator requirements; (2) An Investigator is new to UWA; or (3) UWA finds that an Investigator is not in compliance with UWA’s FCOI policy or management plan.

A FCOI Disclosure Form is required to report an Investigator’s SFIs, as well as those of their immediate family, that reasonably relate to the Investigator’s Institutional Responsibilities. The FCOI Disclosure Form must be submitted to the CRO prior to proposal submission for grant funding or participating in related activities. Additionally, affected UWA employees are required to submit an updated FCOI Disclosure Form:

* Before processing new sponsored research awards or modifications to the scope of work,
* When starting new related activities, or
* Within thirty days of discovering or acquiring any previously unreported SFIs for themselves or their immediate family.

The CRO may also request updated FCOI Disclosure Forms as needed to ensure compliance with the UWA FCOI Policy.

**Review, Determination and Management**

Before an Investigator spends any funds on a sponsored research project, engages in technology commercialization activities, or participates in related activities, the CRO must evaluate the employee’s disclosure of SFIs to determine whether a FCOI exists. To assist with this review, determination, and management, the CRO may consult with the DIO.

The CRO may also involve the Investigator in determining whether a SFI is related to funded research projects or related activities. If a FCOI is identified, UWA will take necessary steps to manage it. This includes the development and implementation of a Management Plan by the DIO, who will also ensure ongoing compliance. For NSF-funded grants, the NSF Office of the General Counsel will be appropriately informed if UWA is unable to satisfactorily manage a conflict of interest and if UWA finds that research will proceed without the imposition of conditions or restrictions when a conflict of interest exists.

Examples of conditions or restrictions that may be imposed to manage a FCOI include, but are not limited to:

* Public disclosure of the conflict (e.g., in research presentations or publications),
* Disclosure to participants in human subjects research as required by the Institutional Review Board, who serves as the monitor of research by independent reviewers,
* Appointment of an independent monitor to protect the integrity of the research design, conduct, and reporting,
* Modification of the research plan,
* Changes to project personnel or responsibilities, or disqualification from certain project activities,
* Reduction or elimination of the financial interest (e.g., sale of equity holdings), or
* Termination of relationships that create the conflict.

**Appeals Process**

Within one week of being notified of the DIO’s decision, the Investigator must either provide written acknowledgement agreeing to comply with the required Management Plan or submit a written request for reconsideration to the DIO. While the DIO cannot alter or remove requirements, they may recommend changes to the CRO and may add additional requirements at their discretion.

After receiving the CRO response, the DIO will issue a final, binding decision on the appeal. The Investigator is entitled to a timely resolution, and the entire reconsideration process—from the submission of the request to the final decision—should be completed within 30 days.

**Retrospective Review**

As required by PHS, FCOIs not disclosed by the Investigator in a timely manner, or not reviewed or managed by the CRO, or failure by the Investigator to comply with terms of a Management Plan, shall be subject to Retrospective Reviews. The Retrospective Review will consider the Investigator's activities to determine whether the SFI is related to research, and if so, whether a FCOI exists. If a FCOI exists, the DIO will implement a Management Plan. If bias is found, UWA is required to promptly notify the PHS awarding agency and submit a mitigation report.

**Enforcement & Sanctions**

The Provost or appropriate Vice President will apply disciplinary procedures, as well as other relevant University disciplinary policies or guidelines, to impose sanctions for violations of the FCOI Policy and related procedures. These sanctions may include suspension, dismissal, or termination from the University.

Additional sanctions may include, but are not limited to:

* Conducting a Retrospective Review and submitting a Retrospective Report as required for PHS agency funded grants,
* Prompt notification to the funding agency of the FCOI and the corrective action taken or to be taken,
* Freezing expenditures from affected funds or terminating sponsored or other agreements,
* Revoking the privilege to engage in research, sponsored activities, technology transfer, commercialization, or other scholarly activities,
* Membership removal from the Institutional Review Board or the Institutional Animal Care and Use Committee,
* Imposing penalties if the FCOI violates the Alabama Ethics Law (Title 36, Chapter 25 of the Code of Alabama 1975)

**Public Accessibility**

This UWA FCOI Policy is available on its publicly accessible website.

Information concerning FCOIs held by senior/key personnel is made publicly accessible by a written response to any requester as required by law. The information provided will include: the Investigator’s name; the Investigator’s title and role with respect to the research project; the name of the entity in which the SFI is held; the nature of the SFI; and the approximate dollar value of the SFI (in pre-specified dollar ranges), or a statement that a value cannot be readily determined. This information will remain publicly accessible for at least three years from the date that it was most recently updated.

**Records Maintenance**

UWA, through the CRO, will retain all FCOI Disclosure Forms and all documentation of actions taken to resolve FCOIs, for at least three years beyond the termination, or completion of the award to which they relate, or until the resolution any of any federally funded agency action involving those records, whichever is longer. These records will be kept confidential to the extent permitted by applicable laws and regulations.