

University Policy on Financial Conflict of Interest

(all research and sponsored proposal submissions)

Federal regulations require that all applicants for funding (grant, cooperative agreements, and contracts) from the Public Health Service (PHS/NIH) or from the National Science Foundation (NSF) have in place policies and procedures that ensure investigators disclose to a designated Institutional Official (IO) any significant financial interest (and those of his/her spouse and dependent children). It is the policy of the University of West Georgia (UWG) that all investigators applying for external funding disclose significant financial interest. It must be emphasized that it is the responsibility of the Investigator and all personnel responsible for the design, conduct or reporting of research under the terms of a federal grant or contract to disclose all Significant Financial Interests (SFI). It is the responsibility of the designated institutional official to make the determination as to whether the disclosed Significant Financial Interests constitute a Financial Conflict of Interest (FCOI). If a conflict of interest exists the institution is required to implement procedures to manage, reduce, or eliminate the conflict of interest prior to the institution's expenditure of any funds under the award.

The UWG policy applies to subcontractors working on federally funded research (see section on subcontractors).

Definitions:

Excluded payer means a Federal, state, or local government agency, a United States institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education.

Financial Conflict of Interest ("FCOI") means any significant financial interest requiring disclosure under this Policy and that UWG, through its Institutional Official, reasonably determines could directly and significantly affect the design, conduct, or reporting of research.

Institution means the University of West Georgia (UWG). The terms Institution and UWG are used interchangeably in this Policy.

Institutional Official ("IO") means the person appointed by UWG, or his/her designee(s), responsible for the oversight and implementation of this Policy. This includes (without limitation) responsibility for the solicitation and review of information from Investigators concerning significant financial interests requiring disclosure. UWG has appointed the Associate Vice President for Research and Sponsored Projects as its Institutional Official. In reviewing and making determinations concerning Investigator disclosures per this Policy, the IO will act in consultation with the university Provost.

Investigator means the project director or principal investigator and any other person, regardless of title or position, who is directly and significantly affect the design, conduct, or reporting of research. This may include collaborators or consultants. The role of individuals involved in research and the degree of independence with which they work is used to determine who should disclose.

Institutional Responsibilities shall mean, as determined by the IO, those activities conducted on behalf of the Institution by an Investigator, including research, activity as a consultant, teaching, professional practice, administrative duties, committee memberships, and service on panels.

Manage means taking action to address an Investigator's FCOI, which can include reducing or eliminating the FCOI, to provide a reasonable expectation that the design, conduct, and reporting of research will be free from bias related to the FCOI.

Research means any systematic investigation, study or experiment designed to develop or contribute to generalizable knowledge, including behavioral and social-sciences research. The term encompasses *basic and applied research* as well as product testing and development. The term includes, but is not limited to, any activity for which research funding is available under grants, cooperative agreements or otherwise, such as a research grant, career development award, center grant, individual fellowship award, infrastructure award, institutional training grant, program project, research resources award or contract.

Senior/key personnel means the PD/PI and any other person identified as senior/key personnel by UWG in the grant application, progress report, or any other report submitted to the federal sponsor by UWG under this policy, including subrecipients or subcontractors.

Significant Financial Interest (SFI) means 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:

- Payments from a publicly traded entity over the 12 months preceding the disclosure that, when aggregated, exceeds \$5,000 as of the date of the disclosure
 - Includes salary and any payment for services not otherwise identified as salary such as;
 - 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;
 - Intellectual Property rights and interests and any payment for services, salary, consulting fees, honoraria, paid authorship.
- Payments from a non-publicly traded entity in the twelve months preceding the disclosure that, when aggregated, exceeds \$5,000
 - Investigator holds any equity interest (e.g., stock, stock option, or other ownership interest)
 - Includes non-profits (such as foundations);
 - Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.
- Investigators also must disclose the occurrence of any reimbursed or sponsored travel paid on behalf of the Investigator (i.e. not reimbursed to the Investigator) regardless of amount, related to UWG responsibilities.

SFI does not include:

- Remuneration from UWG including Intellectual Property rights assigned to UWG and paid by the institution to the Investigator
- Income from investment vehicles (mutual funds, retirement accounts) so long as the Investigator does not control investment decisions made by these vehicles

- Income from teaching engagements, seminars, lectures sponsored by a federal, state, or local government agency, an Institution of higher education, an academic teaching hospital, a medical center, or a research institute;
- Income from service on advisory committees or review panels for a federal, state, or local government agency, an Institution of higher education, an academic teaching hospital, a medical center, or a research institute.

Procedures

Training Requirement for FCOI

Investigators must complete FCOI training prior to submitting an application/proposal for any external funding. Follow-up training is required every three (3) years or immediately in instances where the institutional policy is revised; the PI is not in compliance with the policy or FCOI management plan; or when an investigator is new to the institution.

1. All investigators must complete the CITI Financial Conflict of Interest training provided at <https://www.citiprogram.org/>
2. FCOI “just-in-time” FCOI training will be provided at the request of any funded project member.

Disclosure, Review, and Monitoring Requirement for FCOI

1. Prior to submission of a proposal the PI and any member of the research team who contributes significantly to the design, conduct and reporting of the project will complete the Significant Financial Interest Form. In instances of Significant Financial Interest, the investigator will complete the Financial Conflict of Interest Disclosure Form.
2. FCOI updates will be completed annually for projects funded by NIH or by an Agency using the PHS FCOI Regulations. Personnel on projects funded by other sponsors must update financial disclosures as new reportable significant financial interest are obtained. The Office of Research and Sponsored Projects will maintain a database of PHS funded researchers and send reminders to the project PI in January of each year. Signed forms will be due no later than January 31st of each year.
3. Investigators must disclose within 30 days of discovering or acquiring any new SFI.
4. Disclosure of travel: Investigators must disclose the occurrence of any reimbursed or sponsored travel (i.e., travel which is paid on behalf of the Investigator and not reimbursed to the Investigator so that the exact monetary value may not be readily available), related to the Investigator’s Institutional responsibilities during the previous twelve months, other than travel reimbursed or sponsored by an excluded payer. Travel disclosures must include the purpose of the trip, the identity of the trip’s sponsor or organizer, the trip’s origin and destination, and the duration of the trip. In addition, the Institutional Official may request other information about the trip as necessary to evaluate whether the travel may constitute a Financial Conflict of Interest.

Review of Financial Disclosures

The following process shall apply to financial conflict of interest disclosures submitted by Investigators. The same process will apply if it is the initial submission, an annual renewal, a newly discovered or acquired SFI, or

the submission of a new investigator at UWG. The Institutional Official will review disclosures of SFI related to institutional responsibilities.

1. Determination of Financial Conflicts of Interest.

- a. The IO shall review each disclosed Financial Conflict of Interest; determine whether such conflict relates to funded research, and, if so related, determine whether a Financial Conflict of Interest (as defined below) exists; and
- b. The IO shall determine what conditions or restrictions, if any, should be imposed by the institution to manage, reduce, or eliminate such conflict or interest.
- c. The IO may, depending on the scope of the potential conflict, request that additional staff or faculty serve on an ad hoc review committee to assist in its timely review.

2. Existing Financial Conflict of Interest.

A “Financial Conflict of Interest” exists when the IO reasonably determines that a Significant Financial Interest could directly and significantly affect the design, conduct, or reporting of federally-funded research or educational activities.

3. Management of Financial Conflicts of Interest.

If the IO determines that a Significant Financial Interest constitutes a Financial Conflict of Interest, the IO will work in conjunction with the Provost to develop a management plan. The IO and Provost will review the research, the financial interests in question, and the areas of conflict, and devise a plan for the management of the Financial Conflict of Interest (see “Management Plan” below).

After the fact discovery: In the event a SFI is discovered, whether not disclosed by the investigator in a timely manner or not reviewed by the institution, the IO will: review the significant financial interest; determine whether it is related to the Investigator’s institutional responsibilities; determine whether a financial conflict of interest exists; and, if so will within 60 days:

- i. Implement an interim management plan that specifies the actions that have been, and will be, taken to manage such financial conflict of interest going forward;
- ii. within 120 days of the determination of noncompliance, complete a retrospective review of the Investigator’s activities to determine whether any research, or portion thereof, conducted during the time period of the noncompliance, was biased in the design, conduct, or reporting of such research. If necessary, UWG will update the previously submitted FCOI report, specifying the actions that will be taken to manage the financial conflict of interest going forward. If bias is found, UWG is required to notify the PHS Awarding Component promptly and submit a mitigation report to the PHS Awarding Component. UWG may determine that additional interim measures are necessary.

Management plan

If it is determined by the IO that a SFI creates a FCOI; the IO, in consultation with the Provost, shall assess and determine if a management plan is necessary. If a financial or management conflict of interest exists that would reasonably appear to compromise objectivity of the research, a management plan will be proposed for ensuring research objectivity. Possible strategies include, but are not limited to:

- Public disclosure of the FCOI when presenting or publishing the research

- Disclosure of FCOI directly to potential research subjects
- Monitoring of research by independent reviewers
- Modification of the research plan
- Change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the research
- Reduction or elimination of the financial interest
- Severance of relationships that create financial conflicts

The management plan will be shared with funding agencies, as appropriate.

For studies that are ongoing, when an existing investigator discloses a new SFI, within 60 days the review process described above will be initiated. If a FCOI exists, a management plan will be implemented. If necessary, additional interim measures may be implemented to manage the FCOI between the date of disclosure and completion of the review.

Reporting Requirements

Should any reported conflict or non-compliance require reporting to PHS, the Institutional Official or designee will prepare applicable FCOI report in accordance with PHS regulations. The FCOI reports shall contain information required by law or otherwise by the sponsor. The Investigator should be aware that information pertaining to FCOIs may be disclosed to sponsors or oversight agencies and, in some cases, to the public and may contain such details as the value and nature of the financial interest and elements of the management plan.

If the funding for the Research is made available from a prime PHS awardee (UWG is sub-recipient in funding), such reporting shall be made available to the prime awardee such that they may fulfill their reporting obligations to the PHS.

Financial Conflicts of Interest occurring on projects funded by the NIH will be reported to NIH via the eRA Commons FCOI Module. Reports will be made by the IO or their designee.

Maintenance of Records

In general, records related to the identification, evaluation, and response to FCOI in Research shall be retained for three years following the date that the final Research expenditure report has been submitted to the research sponsor or for a longer period when specified by applicable governmental or University requirements.

Sub-recipient Requirements

When a PHS-funded project for which UWG is the lead institution includes a sub-recipient investigator – whether a sub-grantee, contractor, subcontractor, or collaborator – the sub-recipient investigator is also subject to PHS and NSF FCOI regulations. To ensure compliance, the sub-recipient institution must certify in writing whether sub-recipient investigators will follow the FCOI policy of UWG or the sub-recipient institution; if the sub-recipient institution’s policy will apply, the certification verifies that the policy complies with the PHS and/or NSF FCOI regulation. This certification form will be made available by request from the UWG Office of Research & Sponsored Programs.

UWG employees serving as sub-recipient investigators on PHS-funded research are subject to UWG's FCOI policy; in such a case, UWG investigators may request a certification from the Office of Research & Sponsored Programs to verify their compliance with the UWG FCOI policy and PHS FCOI regulations for the sponsored project's lead institution.

Sub-recipient investigators who are subject to UWG's FCOI policy must fulfill all requirements for investigators as described in this policy, particularly in regards to responsibilities related to the disclosure of SFIs and FCOI training.

For sub-recipient investigators who are subject to their affiliated institution's FCOI policy, sub-recipient institutions must report all identified FCOIs to the UWG Office of Research & Sponsored Programs as soon as possible following internal review of disclosed SFIs and prior to the expenditure of funds. Early reporting will help to ensure timely commencement of funding following a notice of award. For subsequently identified FCOIs, sub-recipient institutions must provide a FCOI report to UWG within 30 days of when a new FCOI is discovered or acquired. FCOI reports made to UWG for sub-recipient investigators must include the following information:

1. Name of the entity with which the investigator has an FCOI
2. Nature of the FCOI (e.g., equity, consulting fees, travel reimbursement, honoraria)
3. Value or estimated value of the financial interest
4. Description of how the financial interest relates to PHS-funded research and the basis for the determination that it conflicts with the research
5. Key elements of the management plan
 - Role and principal duties of investigator in the research project
 - Conditions of the management plan
 - How the management plan will safeguard objectivity in the research project
 - Confirmation of the investigator's agreement to the management plan
 - How the management plan will be monitored to ensure compliance
 - Other pertinent information

In the event a sub-recipient investigator has an FCOI to report, UWG will provide a sub-recipient FCOI report with the above information to the PHS awarding component prior to the expenditure of funds and within 60 days of any subsequently identified FCOI.

Non-Compliance Penalties

All Employees must comply with the Institution's FCOI policy to reduce, manage, and eliminate all potential financial conflicts of interest. In the event an FCOI is present or there has been noncompliance of the FCOI policy, the Employee must cooperate with the management plan set forth to remedy the FCOI or noncompliance. Penalties for noncompliance may include:

1. Cannot submit for externally funded opportunities

2. Termination of the activity that creates the conflict of interest, including inability to draw funds from grant and contract speed types or participate in IRB protocols
3. Funds drawn from a federally funded grant may need to be returned
4. Additionally -
 - Divestiture of significant financial interests.
 - Deactivation of employee's badge access to parking and labs.
 - Disciplinary action against the employee up to and including termination.
 - In the case of violation of criminal or civil law, violation may be subject to civil or criminal penalties.
 - Reporting to applicable federal agencies

Except to the extent required by law and federal regulations, the information disclosed will be kept confidential. You should know, however, that the Institution is required to report the existence of real or potential conflicts of interest to certain federal agencies. Specifically, the NIH (PHS) requires institutions to report to the PHS the existence of any conflicting interests and to assure that the interest has been managed, reduced or eliminated. NSF requires that only conflicts that have not been managed, reduced or eliminated prior to the expenditure of funds under an award be reported to NSF.