

Research Financial Conflict of Interest Procedures

Summary

Georgia College & State University (GC) is committed to preserving the public's trust that the research and activities we conduct is without bias and with the highest scientific and ethical standards. The federal regulations on promoting objectivity in research establishes the standards to provide a reasonable expectation that the design, conduct, and reporting of GC research will be free from bias resulting from investigators' financial conflicts of interest (COI).

Failure to comply with institutional policies and procedures may result in harm to GC's reputation, audit findings, suspension of sponsored activities, closer monitoring by the sponsor, delays in final payments, and/or other enforcement actions imposed by the sponsor. This policy applies to all Federal and non-Federal sponsored activities, including all externally funded activities.

Definitions

An "investigator" is someone:

- defined as the PD/PI and any other person, regardless of title or position
- who is responsible for the design, conduct, or reporting of research funded by PHS, or proposed for such funding
- which may include, for example, collaborators or consultants.

The term "significant financial interest" means anything of monetary value, including, but not limited to, salary or other payments for services (e.g., consulting fees, honoraria, travel or resort admission); equity interest (e.g., stocks, stock options or other ownership interests); and intellectual property rights (e.g., patents, copyrights and royalties from such rights).

The term does not include:

- salary, royalties or other remuneration from Georgia College;
- any ownership interests in the organization, if the organization is an applicant under the Small Business Innovation Research Program (SBIR) or Small Business Technology Transfer Program (STTR);
- income from seminars, lectures, or teaching engagements sponsored by public or non-profit entities;
- income from service on advisory committees or review panels for public or nonprofit entities;
- an equity interest that, when aggregated for the investigator and the investigator's spouse and dependent children, meets both of the following tests:
 - does not exceed \$5,000 in value as determined through reference to public prices or other reasonable measures of fair market value; and
 - does not represent more than a 5% ownership interest in any single entity; or
- salary, royalties or other payments that, when aggregated for the investigator and the investigator's spouse and dependent children, are not expected to exceed \$5,000 during the prior twelve-month period.

A "conflict of interest" exists when Georgia College reasonably determines that a significant financial interest could directly and significantly affect the design, conduct, or reporting of externally sponsored activities.

Elements of complete financial disclosure form includes, if there is significant financial interest:

- The name of the entity with which the investigator has an FCOI
- The nature of the Significant Financial Interest (SFI)
- The value of the financial interest
- Description of how the financial interest may relate to the externally funded research and/or activity.

GC policy designates the COI Committee to review financial disclosures, determine whether a conflict of interest or appearance of conflict of interest exists, and determine what conditions or restrictions, if any, should be imposed by the organization to manage, reduce, or eliminate such conflict of interest. The COI Committee shall meet monthly. The committee shall have a chairperson and shall have representatives from the Office of the Provost, Office of Legal Affairs, Office of Grants and Sponsored Projects, and two representatives from the Faculty.

Examples of conditions or restrictions that may be imposed to manage, reduce or eliminate COI or appearance of COI include, but are not limited to:

- a. public disclosure of significant financial interests;
- b. monitoring of research by independent reviewers;
- c. modification of the research plan;
- d. disqualification from participation in the portion of the externally sponsored activities that would be affected by significant financial interests;
- e. divestiture of significant financial interests; or
- f. severance of relationships that create conflicts.

Procedure

1. OGSP – Grant & Contract Administrator (GCA)
 - a. Will receive initial completed Disclosure Statement that indicate no FCOI from the Investigator(s) at application for inclusion in the grant file.
 - b. Every January, create a list of currently active awards by PeopleSoft project number for each Key Personal as defined by federal policy referenced above.
 - c. Transmit to IT to generate system email
2. IT – Web Development Team
 - a. Merge list from OGSP with custom application to generate system emails
 - b. Alert OGSP that system messages have been sent
3. Senior/Key Personnel
 - a. Review and complete the initial or annual Disclosure Statement
 - b. If there is a SFCOI include the following information:
 - The name of the entity with which the investigator has an FCOI
 - The nature of the Significant Financial Interest (SFI)
 - The value of the financial interest i.e. greater than \$5000
 - c. If applicable, work with assigned institutional official to “manage, reduce, or eliminate” the identified significant financial conflict of interest.
4. OGSP - GCA
 - a. Monitor all disclosure statements for 100% compliance
 - b. Report weekly to the Associate Provost the status of the individuals required to complete forms.
 - c. Add pdf of each disclosure statements to the Project Compliance Subfolder

- d. For any SFI disclosures, prepare FCOI Determination form and forward to COI Committee for review with copy of original disclosure
5. Associate Provost
 - a. Review weekly report from OGSP and engage overdue investigators as needed to ensure 100% compliance with forms completed.
6. COI Committee
 - a. Receive initial and annual completed Disclosure Statement that indicate a disclosed FCOI from the Investigator(s)
 - b. Review responses and consult with the employee to determine if the disclosed financial interest conflicts with the sponsored activity.
 - c. Make recommendations to “manage, reduce, or eliminate” the financial COI or appearance of COI.
 - d. Report identified FCOIs to funder as appropriate per their policies.
 - e. Once the issue has been resolved, return completed FCOI Determination form to OGSP
7. OGSP
 - a. Add a copy of the completed FCOI Review Outcome form to the project’s compliance folder
 - b. Maintain records in accordance with USG record retention policy.

Roles & Responsibilities

It is the role of the Investigators to:

- Complete the Financial Interest Disclosure Statement fully and truthfully
- Alert OGSP and complete an off-cycle disclosure statement, within 30 days of the conflict’s development.

It is the role of OGSP to:

- Use monthly active grants list from the bursar in January to generate email distribution list for all senior/key personnel.
- Monitor all senior/key personnel response for 100% compliance.
- Work with COI Committee as needed to assist with their communication with the sponsors of the affected grants.
- Maintain reports of the disclosure statements in the permanent project compliance file.

It is the role of the COI Committee to:

- Meet monthly and keep meeting minutes
- Review SFI
- Recommend conditions or restrictions to manage, reduce or eliminate COI or the appearance of COI

It is the role of the PI’s supervisor to:

- Read the recommended plan and sign, acknowledging it
- Help to ensure the PI is complying with the plan

It is the role of the Provost to:

- If PI disagrees with recommended plan, PI may appeal in writing to the Provost within five business days. The Provost may affirm or may request the committee to alter its recommendation. If the committee does not agree, the Provost may make a final determination on the recommended plan.

It is the role of the PI to:

- Comply with the plan or else be subject to discipline up to and including termination

Remedy for Non-compliance:

Seven days after the original email is delivered, a reminder will be sent to the outstanding investigators. 14 days from the original email, a second reminder will be sent to the investigator(s) with cc to their immediate supervisor. At 21 days, the issue will be referred to the Associate Provost for further corrective action.