

Georgia College & State University

Financial Conflict of Interest Policy

Policy Overview

Georgia College & State University (GC) is committed to preserving the public's trust that research and activities conducted are without bias and with the highest scientific and ethical standards. It is the Office of Grants & Sponsored Projects' (OGSP) ongoing goal to support research and sponsored activities free of conflict, bias, and foreign influence and to ensure sponsored projects and investigators comply with the GC's Financial Conflict of Interest Policy, and applicable federal regulations (42 CFR Part 50 Subpart F). 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 (FCOI). 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.

Principal Investigators/Program Directors (PI/PDs) and Senior/Key Personnel must be fully transparent about their personal financial affairs (including those of the Investigator's spouse and dependent children), financial support and resources from and affiliations with international institutions, and ensure this information is updated throughout the life of an award.

Definitions

Designated Official is the individual(s) within the Institution who is(are) responsible for the solicitation and review of disclosures of Significant Financial Interests (SFI). The Provost, Grant Manager, and/or other institutional designees as determined by the Provost, will serve as the individual(s) appointed by the university to solicit and review disclosures of Significant Financial Interests, including any related management plan, as applicable, from each Investigator who is participating in or is planning to participate in, Federally Funded Research.

A **financial conflict of interest (FCOI)** arises when an employee (or an employee's spouse or dependent child) has a Significant Financial Interest (SFI) that could directly and significantly affect decision making in the design, conduct, or reporting of externally funded instruction, research, or service activities performed on behalf of the University.

Financial interest is anything of monetary value, whether or not the value is readily ascertainable.

Institutional responsibilities are the Investigator's teaching/education, research, outreach, professional practice, and public service on behalf of the Institution which are in the course and scope of the Investigator's appointment/employment.

Investigator is the Project Director (PD) or Principal Investigator (PI) and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research funded by the PHS or NSF, or proposed for such funding. This definition is not limited to those titled or budgeted as principal investigator or co-investigator on a particular proposal, and may include postdoctoral associates, senior key personnel, or graduate students. The definition may also include collaborators or consultants as appropriate.

Research means a systematic investigation, study, or experiment designed to develop or contribute to general knowledge relating broadly to any discipline of scholarly endeavor. This term encompasses basic and applied research and product development. As used in this Policy, “research” includes any such activity for which funding is sought, available, or offered from external sources.

Significant Financial Interest (SFI) is a financial interest consisting of one or more of the following interests of the Investigator that reasonably appears to be related to the Investigator's Institutional Responsibilities.

Determining Significant Financial Interest (SFI)

- With regard to any publicly traded entity, SFI exists 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 per entity, exceeds \$5,000. For purposes of this definition, remuneration includes:
 - salary; or
 - any payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorship); or
 - 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.
- With regard to any non-publicly traded entity, SFI exists:
 - if the value of any remuneration received from the entity in the twelve months preceding the disclosure, when aggregated per entity, 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
 - Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.
- The occurrence of any reimbursed or sponsored travel, the value of which per entity exceeds \$5,000¹, related to their institutional responsibilities. This disclosure requirement does not apply to travel that is reimbursed or sponsored by:

¹ NIH Provides Policy Clarification Concerning Disclosure Requirements for Reimbursed and Sponsored Travel - 42 CFR Part 50 Subpart F, "Responsibility of Applicants for Promoting Objectivity in Research for Which PHS Funding is Sought" Notice Number: NOT-OD-13-004 Key Dates Release Date: October 18, 2012 "Institutions may, within the discretion afforded by the Final Rule, impose the \$5,000 de minimis threshold to reimbursed or sponsored travel disclosure in their institutional policies which specify the disclosure details. For example, consistent with the requirement for other types of financial interests within the regulatory definition of SFI, Institutions could apply the de minimis threshold when aggregated per entity. Disclosure of reimbursed or sponsored travel is also subject to the exclusions described in 50.603(3)."

- a Federal, state, or local government agency, an Institution of higher education as defined at 20 U.S.C. 1001(a);
- an academic teaching hospital, a medical center; or
- a research institute that is affiliated with an Institution of higher education.
- SFI does not include:
 - Salary, royalties, or other remuneration paid by the Institution to the Investigator if the Investigator is currently employed or otherwise appointed by the Institution, including:
 - intellectual property rights assigned to the Institution and
 - agreements to share in royalties related to such rights;
 - Income from 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;
 - Income from seminars, lectures, or teaching engagements sponsored by a Federal, state, or local government agency, an Institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education; or
 - Income from service on advisory committees or review panels for a Federal, state, or local government agency, an Institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education.

Sponsored activity is a research, creative activity, training, or instructional and service project involving funds, materials, or other compensation from one or more outside sources (sponsors).

Scope and Compliance

Though this policy aligns with financial conflict of interest regulations related to Public Health Service (PHS)² funded research, this policy applies to all investigators who apply for and/or receive instruction, research, or service funding or other support from external agencies or organizations and applies to new and ongoing sponsored activities funded by external agencies or organizations regardless of the date that such activities were initiated. During proposal development and award management meetings, investigators will be made aware of the FCOI policy, federal regulations, training requirements, and the investigator's disclosure responsibilities. This Policy requires an annual disclosure of all Financial Conflicts of Interest (FCOIs) by any GC employee acting in the role of an Investigator on proposals submitted to and funded by an external entity.

² Administration for Children and Families (ACF); Administration on Aging (AoA); Agency for Healthcare Research and Quality (AHRQ); Agency for Toxic Substances and Disease Registry (ATSDR); Centers for Disease Control and Prevention (CDC); Centers for Medicare & Medical Services (CMS); Federal Occupational Health (FOH); Food and Drug Administration (FDA); Health Resources and Services Administration (HRSA); Indian Health Services (IHS); National Institutes of Health (NIH); Substance Abuse and Mental Health Services Administration (SAMHSA); also see 42 CFP Part 50 and 45 CFR Part 94

The FCOI Committee

The FCOI committee shall have a chairperson and representatives from the Office of the Provost, Office of Legal Affairs, Office of Grants and Sponsored Projects, and two representatives from the faculty. Each member of the committee shall be disinterested in any case under review and shall be free of financial or supervisory ties to conflicted investigators. For cases where a committee member must excuse themselves, the FCOI committee chairperson shall seek an interim member to review that case. The FCOI committee shall present determinations to the Associate Provost for Academic Affairs.

Training

Investigators covered by this policy are required to complete Financial Conflict of Interest training prior to engaging in sponsored research projects and every four years thereafter. Investigators may fulfill the training requirement by reviewing this policy and completing the [Financial Conflict of Interest Training Module offered by CITI](#) and providing a certificate of completion to the Designated Official via the grant submission process. An Investigator may also be required to repeat this training as part of a management plan. Investigators will be required to complete this training immediately if:

- The university's Financial Conflict of Interest policy changes in a manner that affects Investigator requirements;
- The Designated Official finds an Investigator noncompliant with the university's Financial Conflict of Interest policy or management plan; or
- An Investigator is new to the university.

The Designated Official as defined in this policy will also complete the CITI training and any other training as determined to assist them in determining what qualifies as a Financial Conflict of Interest.

Disclosure Procedures

All investigators (PDs and Senior/ Key Personnel) are required to disclose any significant financial interests (SFI) as well as those of their spouse and dependent children related to their institutional responsibilities that meets or exceeds the regulatory definition of SFI. This disclosure will be made through completion of a Financial Conflict of Interest (FCOI) Disclosure form. This [FCOI Disclosure Form](#) is located on the OGSP website.

These disclosures should be made:

- At the time of application
- At time of award notice and acceptance
- Annually each January
- Within 30 days of discovering or acquiring a new SFI
- When new investigators are added to ongoing research projects

Financial Conflict of Interest (FCOI) Disclosure Form

Elements of complete financial disclosure form include, 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*

Disclosure Review

GC policy designates the Financial Conflict of Interest (FCOI) Committee to review all SFI disclosures, determine whether an FCOI or appearance of FCOI exists, and determine what conditions or restrictions, if any, should be imposed to manage, reduce, or eliminate such conflict of interest prior to expenditure of any funds. The committee will utilize an FCOI Determination form and process to review disclosures for determination of an FCOI. The committee may contact the investigator to request additional information deemed necessary to evaluate whether the SFI constitutes an FCOI. If the committee determines there is existence of an FCOI, they shall notify any other appropriate compliance committee (IRB, IACUC, etc.). These separate compliance committees maintain discretionary authority over matters under their purview.

For disclosures identified as not having been disclosed timely, and those not previously reviewed by the institution (e.g., an investigator new to the funded project or a new FCOI acquired by an existing investigator), the FCOI committee must complete the process of review through implementation of a management plan (if applicable) within 60 days.

Management of Financial Conflicts of Interest

When the FCOI committee determines that an SFI is an FCOI, a management plan must be developed and agreed to by the conflicted investigator before (s)he can proceed with research activities or request expenditure of funds under a PHS-funded project. Management plans should describe the SFI and explain how it creates an FCOI in the research, the role of the conflicted investigator on the project, the rationale for including the conflicted investigator in the project, an explanation of why the FCOI cannot be eliminated, the conditions of the plan and how these conditions will safeguard research objectivity, and confirmation of investigator's agreement to the plan.

The committee shall determine conditions of the management plan and shall oversee implementation of the plan for investigators and subrecipient investigators. In order to develop the management plan, the committee may contact the investigator to request additional information about the conflict or about proposed research activities. Failure of the investigator to comply within 3 business days will constitute a violation of this policy. The committee will monitor the plan for compliance through project completion and will review current management plans annually and provide a brief report to the OGSP. The FCOI committee has the final discretion to determine management plan conditions, which are enforceable as part of FCOI policy. Copies of the plan will be provided to the investigators and appropriate units (IRB if human subjects are involved, etc.).

In cases where an FCOI is identified untimely (research activities have begun), the committee may work to immediately mitigate or cease research activities until an interim or final management plan can be implemented.

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

- a. Public disclosure of significant financial interests, including to sponsors, collaborators, and human subjects;
- 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;
- f. Reassignment of duties that could exacerbate the conflict;
- g. Temporary placement of holdings in a blind trust; or
- h. Severance of relationships that create conflicts.

Retrospective Review

The institution shall, within 120 days of determination of noncompliance, complete a retrospective review of the investigator's activities and the funded research project to determine whether any funded research, or portion thereof, conducted during the time period of the noncompliance, was biased in the design, conduct, or reporting of such research. The following activities may constitute a retrospective review:

- an FCOI is not identified or managed in a timely manner
- the Investigator fails to disclose an SFI that is determined by the institution to constitute an FCOI
- failure by the investigator to comply with an FCOI management plan
- failure by the institution to review or manage the FCOI

The retrospective review shall include the project number, project title, PD/PI name, name of conflicted investigator and entity with which the investigator holds the SFI, reasons for the retrospective review, detailed methodology used for review, findings and conclusions of the review, and an explanation of the impact of any bias on the project or the university's actions to eliminate or mitigate the impacts of the bias. This report shall be submitted to the funding agency according to their guidelines.

For any funded project of clinical research whose purpose is to evaluate the safety or effectiveness of a drug, medical device or treatment has been designed, conducted, or reported by an investigator with an FCOI that was not managed or reported by the institution, the institution shall require the conflicted investigator to disclose the FCOI in each public presentation of the results and to request an addendum to published reports or presentations.

Sanctions

Sanctions for policy violations may include those permissible through USG or institutional policy, from administrative intervention up to termination of employment.

The FCOI committee shall also make recommendations to ameliorate the impact of the policy violation or any impact of the FCOI on the research. These recommendations may include revision to a management plan.

Reporting

Initial, annual, and revised reports

The OGSP must provide the sponsor a report about any FCOI in a funded project. OGSP will send all initial, annual (ongoing), and revised FCOI reports to the funder prior to the start of project activities or the expenditure of any funds under a funded project. Details of these reports will include any SFI found to be an FCOI and any efforts to reduce or manage the FCOI. FCOIs that have been eliminated prior to fund expenditure shall not be reported.

For disclosures that previously have not been reviewed (e.g., new FCOIs for existing investigator or an investigator new to the funded project), OGSP shall send the funder a report regarding the FCOI and management plan within 60 days.

Reports shall include sufficient information about the nature and extent of the FCOI and the institutional management plan, including:

- Entity's Name;
- The project number, PD/PI name;
- Name of investigator with FCOI and entity to which the FCOI applies;
- Nature of the financial interest (e.g., consulting, travel, etc.) and the value of the financial interest;
- How the interest relates to the PHS-funded research and the basis for determining the existence of an FCOI; and
- Description of the FCOI management plan, including role and duties of the conflicted investigator related to the research project, the elements of the management plan and how it will safeguard objectivity during the project, evidence of investigator agreement with the plan, and details about management plan compliance monitoring.

Annual (ongoing) project reports should be submitted for project duration and should address the status of the FCOI, any management plan changes, and explanation if the FCOI has been eliminated or no longer exists.

Reports will be immediately sent to the funder if outside these reporting mechanisms any bias is found with the design, conduct, or reporting of funded research. In addition, a mitigation report is also required at that time. If an investigator fails to comply with the FCOI policy or

management plan and appears to have been biased in the design, conduct, or reporting of the funded project, the funder will be notified immediately and corrective action will be taken.

Policy Violations

Violations of this policy are defined as:

- Failure to disclose an SFI that may affect the objectivity of the research, or failure to disclose the SFI in a timely manner
- Failure to comply with any review, management plan, information or investigatory actions or requests assumed under this policy, or failure to comply in a timely manner
- Provision of incomplete or incorrect information knowingly that pertains to actions under this policy

Investigation of violations:

Any employee of the university who becomes aware of a potential violation of the FCOI policy should immediately notify the Director of Grants and Sponsored Projects. The committee shall investigate to determine if a policy violation occurred.

The investigation should consist of an interview with the person alleging the violation and the investigator who is the subject of the allegation. Failure of the investigators to respond to requests for interviews within 3 business days will constitute a violation of this policy. During the investigation, the FCOI committee has the discretion to suspend research activities through the conclusion of the investigation.

If a policy violation is found, the committee shall submit a report describing the results of the investigation to the Associate Provost for Academic Affairs, who shall fashion a sanction, as appropriate, to include but not be limited to, a letter of reprimand which shall be placed in the employee's official file and/or restriction on the use of funds.

Appeals

Any investigator affected by a decision of the FCOI committee or the OGSP under this policy has the right to appeal the decision to the Vice President of Academic Affairs (the Provost) within five business days of the decision notification. The Provost or their designee may review any such decision and may affirm or rescind the decision, or may request the committee to alter its recommendation if they determine it is inappropriate or inconsistent with this policy or applicable federal law or regulations. The Provost shall provide a written explanation for their decision and their decision shall be final and further appeals within the institution are prohibited.

Records

All FCOI-related records will be maintained for at least three years from submission of the project final expenditure report date. FCOI records will not only include all investigator disclosures but also the Committee's review and response to the disclosures, whether or not an

FCOI was determined. For quarterly or annually renewed awards, records will be kept at least three years from submission of the quarterly or annual financial report.

Subrecipients

All subrecipients are required to follow PHS-compliant FCOI policies. They must establish a written agreement stating they will follow their home institution's PHS-compliant FCOI policy. This written agreement shall state that the home institution's FCOI policy complies with all applicable rules, regulations, and laws (including, but not limited to, 42 CFR Part 50 and 45 CFR Part 94). The agreement shall also outline the timeframe required for disclosures to ensure proper compliance, reporting, and management. If the subrecipient's home institution does not have a PHS-compliant FCOI policy, they are required to follow GC's FCOI policy, and are subject to the same parameters in this policy as other investigators (including training, etc.).

Public Disclosure and Accessibility

This FCOI policy shall be maintained on a publicly available website. The OGSP shall ensure the website contains the most recent version of this policy.

The Institution will make available upon written response to any requestor within five business days of a request, information concerning any SFI that meets the following criteria:

- The SFI was disclosed and is still held by the Investigator;
- A determination has been made that the SFI is related to the funded research; and
- A determination has been made that the SFI is an FCOI.

Information that the Institution makes available upon written response to any requestor within five business days of a request shall include, at a minimum, the

- Investigator's name;
- Investigator's title and role with respect to the research project;
- Name of the entity in which the significant financial interest is held;
- Nature of the significant financial interest; and
- Approximate dollar value of the significant financial interest (dollar ranges are permissible: \$0-\$4,999; \$5,000-\$9,999; \$10,000-\$19,999; amounts between \$20,000-\$100,000 by increments of \$20,000; amounts above \$100,000 by increments of \$50,000), or a statement that the interest is one whose value cannot be readily determined through reference to public prices or other reasonable measures of fair market value.

Information concerning the SFI of an Investigator shall remain available for responses to written requests at least three years from the date that the information was most recently updated.

Confidentiality

Disclosure forms, conflict management plans, and related information will be confidential to the extent possible. However, the Institution will disclose such information to an agency funding the research, to a requestor of information concerning FCOI related to PHS or NSF

funding or to the primary entity who made the funding available to the Institution if required by law, and then, only to the extent required by the law. If the Institution is requested to provide disclosure forms, conflict management plans, and related information to an outside entity, the Investigator will be informed of this disclosure.

Effective Date

This policy is effective as of July 1, 2022.

Resources

- [NIH's Checklist for Policy Development Related to the 2011 Revised Financial Conflict of Interest \(FCOI\) Regulation](#)
- [42 CFR Part 50 Subpart F - Promoting Objectivity in Research](#)
- [NIH's Protecting U.S. Biomedical Intellectual Innovation](#)
- [NSF's Proposal & Award Policies & Procedures Guide \(PAPPG\)](#)
- [NSF's Frequently Asked Questions guide](#)