

Overview: In the summer of 2012, the Department of Health and Human Service (DHHS) required Institutions to inform each Investigator of their Institution's policy on Financial Conflicts of Interest, the Investigator's responsibilities regarding disclosure of Significant Financial Interests, and require each Investigator to complete training regarding the same prior to engaging in research related to any Public Health Service (PHS)-funded projects every four years.

Instructions: You are instructed to carefully read each regulation, policy, and procedure. As part of your Annual COI Certification, you will be asked to certify that you have read, understood, and will comply with the Federal regulations and the Georgia Institute of Technology (Institute) policies and procedures regarding Investigator's responsibilities for disclosing significant financial interests. Please contact the Conflict of Interest Management Office should you have any questions regarding the below regulations and/or policies.

Email: coi@gatech.edu

Phone: 404-894-4819

- **Department of Health & Human Service Final Rule on the Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is Sought (42 C.F.R. Part 50, Subpart F) and Responsible Prospective Contractors (45 C.F.R. Part 94)**

http://grants.nih.gov/grants/policy/coi/fcoi_final_rule.pdf

- **Institute Policy 5.6: Conflict of Interest and Outside Professional Activity Policy**

<http://www.policylibrary.gatech.edu/faculty-handbook/5.6-conflict-interest-and-outside-professional-activity-policy#node-1737>

- **Investigator's Responsibilities**

- **Who Must Complete the Investigator Financial Interest in Research Report Form?**

At a minimum, the term *Investigator* includes the following:

- Project Directors, Principal Investigators, and/or members of the research team identified as senior/key personnel on the grant or contract application, progress report, or any other report;
- Individuals identified by the Principal Investigator or Project Director who are responsible for the design, conduct or reporting of the research, such as Collaborators or Consultants named on the grant; and
- The Investigator must report Significant Financial Interests for himself/herself and for his/her spouse or partner and dependent children that are related to the Investigator's institutional responsibilities.

- **What Must Be Reported?**

The following Significant Financial Interests in entities related to an Investigator's teaching, research, administrative, or clinical duties at the Institute must be reported:

- \$5,000 or more including salary; consulting fees; honoraria; and/or gifts received within the past 12 months (excluding salary, grant support, and other payments for services received from the Institute);
- Equity or ownership interest (including stock options) worth \$5,000 or more as determined by reference to the entity's publicly listed price (excluding mutual funds);
- Any equity or ownership interest in an entity if the entity's value cannot be determined by reference to publicly listed prices (e.g., privately held companies, such as start-up companies);
- A position as director, officer, partner, trustee, employee, or any other position of management;

- Receipt of patent/copyright licensing fees or royalties from an entity or for a technology related to an Investigator's teaching, research, administrative, or clinical duties at the Institute;
 - Any compensation whose value could be affected by the outcome of the research; and
 - PHS Investigators must disclose sponsored and reimbursed travel
- **When Should This Be Reported?**
- Each Investigator should report any Significant Financial Interest *prior to* submitting a formal proposal to any proposed sponsor of the research; or
 - Prior to conducting the research, if the research is internally funded.
 - Investigators are required to update their reports in real time to reflect changes in or additions of Significant Financial Interests Requiring Disclosure. In cases where Investigators are not aware of the existence of a Significant Financial Interest at the time of a proposal, or if the Significant Financial Interest develops after submission of a proposal, then Investigators shall report the interest to the COI Review Office within 30 days of learning of the interest. This can be done by amending the Investigator Financial Interest in Research Report in the eCOI system.
 - Each year of a grant or contract, an Investigator must update his/her Investigator Financial Interest in Research Report. The form must be updated at the time of the annual progress report, twelve (12) months after the notice of award, or the initiation of research, whichever date is earliest.
- **Consequences of Non-Compliance**
- Failure to make the necessary disclosure or follow an agreed upon management plan is a violation of Institute policy.
 - Any Employee who violates this policy shall be subject to disciplinary action up to and including dismissal.

Required PHS Procedures for failure to comply with policy or management plan

In addition the above review and sanctions, Institute and PHS Investigators are subject to the following procedures when a Financial Conflict of Interest (FCOI) is not identified or managed in a timely manner including failure by the Investigator to disclose a Significant Financial Interest that is determined by the Institute to constitute a Financial Conflict of Interest; failure by the Institute to review or manage such a FCOI; or failure by the Investigator to comply with a FCOI management plan.

- A. The Institute must implement, on at least an interim basis, a management plan that shall specify the actions that have been, and will be, taken to manage such FCOI going forward.
- B. Within 120 days of the Institute's determination of noncompliance, the Institute must complete a retrospective review of the Investigator's activities and the PHS-funded research project to determine whether any PHS-funded research, or portion thereof, conducted during the time period of the noncompliance, was biased in the design, conduct, or reporting of such research.
- C. The Institute must document the retrospective review and include a detailed methodology used for the retrospective review (e.g., methodology of the review process, composition of the review panel, documents reviewed).
- D. Based on the results of the retrospective review, if appropriate, the Institute shall update the previously submitted FCOI report, specifying the actions that will be taken to manage the FCOI going forward. The Conflict of Interest Management Office shall contact the Office of Research Compliance and Assurance and alert them of the findings of the retrospective review.

If the retrospective review team members find bias, the Institute is required to notify the PHS Awarding Component promptly and submit a mitigation report to the PHS Awarding Component. The mitigation report must include, at a minimum, the key elements documented in the retrospective review, a description of the impact of the bias on the research project, and the Institute's plan of action or actions taken to eliminate or mitigate the effect of the bias (e.g., impact on the research project; extent of harm done, including any qualitative and quantitative data to support; analysis of whether the research project is salvageable). Thereafter, the Institute will submit to the PHS Awarding Component FCOI reports, as specified by the PHS regulations. Depending on the nature of the FCOI, the Institute may determine that additional interim measures are necessary with regard to the Investigator's participation in the PHS funded research project between the date that the FCOI or the Investigator's noncompliance is determined and the completion of the Institute's retrospective review.