



Policy Name	Financial Conflict of Interest
Policy Number	12000.020
Effective Date	May 23, 2017
Administrative Division	Division of Research and Federal Relations
Unit	Research Compliance
Revised Date	Click here to enter text.

1.0 Policy Statement

The University is responsible for promoting objectivity in research and protecting the reputation of the research enterprise through the proper management of financial conflicts of interest. This responsibility is shared by the University research staff, and therefore, all are required to fully disclose all of his/her own real, apparent or potential significant financial interests and those of his/her spouse and dependent children annually and to update their disclosures when circumstances change.

2.0 Purpose

The objective of this policy is to outline the University's specific requirements for disclosures, monitoring, reporting and training requirements for the management of financial conflict impacting sponsored research. Specific requirements are stated in accordance with applicable regulations outlined by the [Public Health Services \(PHS\) at 42. C.F.R. Part 50 Subpart F](#) and the [National Science Foundation \(NSF\) Financial Disclosure policy](#).

3.0 Definitions

- 3.1 Disclosure – to provide relevant information about one's financial interests related to a research project to parties inside and outside the University to assure full awareness of potential conflicts and institutional efforts to address and manage them.
- 3.2 Investigator - the project director or principal Investigator, co-investigator and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of funded research, or proposed for such funding, which may include, for example, collaborators or consultants.
- 3.3 Financial Conflict of Interest (FCOI) - a significant financial interest that could directly and significantly affect the design, conduct, or reporting of funded research.
- 3.4 Financial Interest - anything of monetary value, related to an investigator's institutional responsibilities, whether or not the value is readily ascertainable, in any of these categories.
- 3.5 Institutional responsibilities - an Investigator's professional responsibilities on behalf of the Institution, which may include, for example: activities such as research, research consultation, teaching, professional practice, institutional committee memberships, and service on panels such as Institutional Review Boards or Data and Safety Monitoring Boards.

- 3.6 Researcher - includes the principal investigator and all faculty and research staff members who will have responsibility for the design and conduct of the research as well as the dissemination of its results.
- 3.7 Significant Financial Interest (SFI) - consists 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:
 - 3.7.1 With regard to any publicly traded entity, a significant financial interest exists if the value of any salary and any payment for services, for consulting fees, honoraria, paid authorship, or any equity interest including stock, stock options or other ownership interest, as determined through reference to public price or other reasonable measures of fair market value exceeds \$5,000.
 - 3.7.2 With regard to any non-publicly traded entity, a significant financial interest exists 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
 - 3.7.3 Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.
- 3.8 Senior/Key Personnel - the project director or principal investigator and any other person identified as responsible for the design, conduct or reporting of a research study by the Institution in the grant application, progress report, or any other report submitted to the PHS by the Institution under the regulation.
- 3.9 Immediate Family - the immediate family of a Faculty or Staff member includes his or her spouse, parents, stepparents, siblings, children, stepchildren, grandchildren, grandparents, sons-in-law, daughters-in-law, mother-in-law, father-in-law, brothers-in-law and sisters-in-law.
- 4.0 Additional Information
 - 4.1 All Principal Investigators and research staff participating in a sponsored project covered by this policy must disclose whether or not he or she has external affiliations that may constitute a conflict.
 - 4.2 Research staff is required to disclose SFI at the time of the application or proposal for NIH and National Science Foundation funded research and prior to incurring costs on an award or issuance of a subcontract.
 - 4.3 All Financial Conflicts of Interest will be reported to the funding agency in accordance with the terms of the agreement and federal regulations.
 - 4.4 Research staff members covered by this policy must submit an updated disclosure of significant financial interests at least annually during the period of the award. Any information that was not disclosed initially should be provided and should also include updated information on previously disclosed SFI.

- 4.5 All funded investigators, senior/key personnel should complete mandatory online training prior to engaging in any research related to any funded grant and at least every four years.
 - 4.6 Research staff covered by this policy may have to re-certify immediately if revisions to this policy affect the requirements, new employment with the University or if the research staff member is not in compliance with this policy or an implemented management plan.
 - 4.7 Prior to incurring expenditures on any awards issued to the University, Research Compliance will review all disclosures to determine whether a financial conflict of interest exists and if so develop and implement a management plan.
 - 4.8 A retrospective review of research will be performed on undisclosed Financial Conflicts of Interest that are not reported or managed in a timely manner. The Research Compliance Officer will complete the review documenting the noncompliance to determine whether the research was biased in its design, conduct or reporting of such research.
 - 4.9 If any biases are identified due to the failure to comply with this policy, the awarding agency will be notified and a mitigation report describing the impact of the bias on the research project and the actions taken or to be taken to eliminate or mitigate the effects of the bias. The University will also update any previously submitted FCOI report regarding the actions taken to manage the conflict of interest going forward.
 - 4.10 Investigators must disclose the occurrence of any externally sponsored travel related to their institutional responsibilities. The disclosure should include the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration.
 - 4.11 All implemented management plans will be monitored on an ongoing basis until the completion of the research.
 - 4.12 Sanctions may be imposed if Research staff members fail to make disclosures in a timely manner or submit false disclosures or is otherwise in non-compliance with the implementation of a management plan.
 - 4.13 Willful concealment of financial interests may result in disciplinary actions and sanctions may be imposed upon the violating individual.
 - 4.14 The University must ensure that its Subcontractors comply with federal regulations regarding Financial Conflicts of Interest. The terms of the written agreement/contract issued must clearly state if the University FCOI policy is applicable or that of the subrecipient. The subrecipient must certify that its policy complies with federal regulations outlined in Subpart F. If certifications are not provided, the agreement will state that the subrecipient is subject to the University's policy.
- 5.0 Employee Adherence
- Employees are required to adhere to these guidelines. Willful disregard of this policy shall be considered non-compliance and may result in a formal reprimand up to and including termination. The information stated in this policy pertains and applies to applicable employees, departments and funding sources of the University.