

Scope

This Policy on Financial Conflict of Interest in Research applies to members of Stowers Institute for Medical Research (“Institute”) and to individuals who make substantial use of the Institute’s facilities, such as independent contractors, visiting scientists, postdoctoral fellows and approved visitors (collectively, “Covered Individuals”).

Purpose

The Institute is committed to conducting research consistent with the highest standards of ethics and in compliance with legal requirements, including those imposed by external funding sources. In furtherance of that commitment and in compliance with those requirements, this policy provides procedures for disclosure of significant financial interests by Covered Individuals engaging in research activities at the Institute, determining whether those interests constitute a real or perceived financial conflict of interest and if so, addressing the financial conflict of interest so that the research activities are conducted free of bias.

Policy**Definitions**

Agency-funded Research: Research funded by the Public Health Service (“PHS”) (National Institutes of Health (“NIH”)), the National Science Foundation (“NSF”) and any other agency that applies the PHS Rule.

Bias: circumstances under which a Researcher would experience (or could appear to experience) impaired professional judgment or objectivity resulting from an FCOI which could directly and significantly affect the design, conduct or reporting of Research in which the Researcher is involved, as determined by the Institute.

Excluded Financial Interest: A Significant Financial Interest does not include, among other things, (i) income from investment vehicles such as mutual funds and retirement accounts, as long as the Researcher does not directly control the investment decisions made by the investment managers within these funds or accounts, or (ii) income from seminars, lectures, teaching engagements or service on advisory committees or review panels sponsored by, or travel that is reimbursed or sponsored by, a government agency (federal, state or local); an institution of higher education as defined at 20 USC § 1001(a); or an academic teaching hospital, medical center or research institute that is affiliated with an institution of higher education.

Family: spouse, minor children and other persons living in the same household or financially dependent upon a Covered Individual.

Financial Conflict of Interest (FCOI): any situation in which a Significant Financial Interest of a Researcher (or a member of his or her Family) has the potential to result in (or could appear to result in) Bias in the design, conduct or reporting of Research in which the Researcher is involved, as determined by the Institute.

Financial Interest: anything of monetary value, including, but not limited to, salary or other payments for services (e.g., consulting fees, honoraria, paid authorship); equity interests (e.g., stocks, stock options or other ownership interests); intellectual property rights (e.g., patents, copyrights), upon receipt of income related to those rights and interests; and reimbursed or sponsored travel.

Institutional Official(s): the General Counsel, Scientific Director and/or the President and CEO of the Institute, acting individually or in concert with one or both of the other two Institutional Officials, and if considered appropriate by one or more Institutional Officials, with the involvement of the Executive Committee of the Board of Directors of the Institute.

PHS Rule: the PHS Final Rule on the Responsibility of Applicants for Promoting Objectivity in Research for which Public Health Service Funding is Sought (42 CFR part 50, subpart F,) issued on August 25, 2011.

Research: Institute research activities, regardless of whether those activities are externally or internally funded, including, but not limited to, the design, conduct and reporting of those research activities.

Researcher: a principal investigator or other Covered Individual, regardless of title or position, who is responsible for the design, conduct or reporting of Research.

Senior/Key Personnel: the principal investigator(s) of Agency-funded Research and any other Covered Individual identified as senior or key personnel in the grant application, progress report or any other report submitted to the relevant funding agency.

Significant Financial Interest: a Financial Interest that rises to level of a Significant Financial Interest as defined in 42 CFR § 50.603. In general, a Significant Financial Interest is a Financial Interest that (i) is held or received, directly or indirectly, by a Researcher and/or his or her Family members in or from a third party, (ii) is related (or could appear to be related) to the Researcher's responsibilities to the Institute, and (iii) is not an Excluded Financial Interest.

General Procedures for All Researchers

The following procedures apply to all Researchers, whether their Research is externally or internally funded.

Disclosure of Financial Interests. In order to identify and manage FCOIs, each Researcher is required to submit a Disclosure of Significant Financial Interests (Form F202L) to the Office of the General Counsel (i) on or before the date he or she is hired, appointed or otherwise becomes associated with the Institute, (ii) annually thereafter, upon solicitation by the Institutional Official(s), and (iii) within 30 days of any material change in the information disclosed or acquisition of a new Significant Financial Interest.

Review of Significant Financial Interest Disclosures. The Institutional Official(s) will review the submitted disclosure statements and determine whether an FCOI exists and whether additional information is required from the Researcher. The review will take into account the nature and extent of the Significant Financial Interest(s), the nature of the Research which could affect the Significant Financial Interest(s), and the nature and extent of the Researcher's role in the Research. If it is determined that an FCOI exists, the Institutional Official(s) may require the Researcher to comply with a management plan to ensure the mitigation or elimination of the FCOI to ensure, to the extent possible, that the design, conduct and reporting of Research will be free from Bias.

Training. Researchers must complete the FCOI training provided by the Institute promptly after he or she is hired or appointed by the Institute or otherwise becomes associated with the Institute. A Researcher must also complete FCOI training immediately if he or she violates a management plan or otherwise fails to comply with this policy.

Non-compliance. Failure by a Researcher to comply with this policy, including, but not limited to, failure to submit a Disclosure of Significant Financial Interest when required; failure to provide additional information when requested; knowingly filing an incomplete, erroneous or misleading disclosure statement; or failure to comply with an FCOI management plan, may result in disciplinary or other adverse action being taken against the Researcher. Such action could result in, among other things, a formal reprimand, non-renewal of appointment, or termination of employment, appointment or other association with the Institute, in addition to any enforcement action mandated by a grant funding agency.

Confidentiality. To the extent permitted by this policy and applicable law, the Disclosure of Significant Financial Interests and related records and information submitted by a Researcher pursuant to this policy will be maintained as confidential.

Additional Procedures for All Principal Investigators and for All Researchers Conducting Agency-funded Research

If a Researcher engages in Agency-funded Research, the following additional procedures must be followed and in the event of a conflict between these additional procedures and the general procedures set forth above, these additional procedures will govern.

Training. The Researcher must complete FCOI training prior to engaging in Agency-funded Research, no less often than every four years and promptly after this policy is revised in any manner that affects the requirements of Researchers.

Disclosure of Financial Interests, Including Reimbursed or Sponsored Travel. Prior to the submission of a proposal for NIH or NSF funding, a Researcher must submit a Statement of Significant Financial Interests to the Office of the General Counsel. Each Disclosure of Significant Financial Interests, whether submitted in connection with the submission of a grant funding proposal or otherwise, must also disclose all occurrences of reimbursed or sponsored travel except those reimbursed or sponsored by an academic institution or by a U.S. federal, state or local government agency for the Researcher and any Family member which is related (or could appear to be related) to the Researcher's responsibilities to the Institute. The disclosure must include, at a minimum, the purpose, destination and duration of the trip, and the identity of the sponsor/organizer.

Review of Significant Financial Interest Disclosures. When a new Significant Financial Interest is disclosed during the course of Agency-funded Research, the Institute will conduct its review and, if necessary, implement an interim management plan within 60 days of disclosure. The Institute will also conduct its review and, if necessary, implement an interim management plan within 60 days of disclosure if it identifies a Significant Financial Interest that was not disclosed timely by a Researcher or was not previously reviewed or managed by the Institute during Agency-funded Research. As part of its review, the Institute will determine whether the Significant Financial Interest is related to Agency-funded Research (i.e., the Significant Financial Interest could be affected by the Agency-funded Research or is in an entity whose Financial Interest could be affected by the Agency-funded Research.)

Management of FCOIs. For any identified FCOI, the Institute will take appropriate action to manage an FCOI in order to reduce the potential for it to compromise the safety or validity of the Agency-funded Research consistent with the requirements of 42 CFR § 50.605(a). If the Institute implements a management plan, it will monitor Researcher compliance with the management plan on an ongoing basis until the completion of the Agency-funded Research. For NSF-Agency-funded Research, the Institute may allow the research to go forward without imposing such conditions or restrictions if the Institute determines that imposing conditions or restrictions would be either ineffective or inequitable, and that the potential negative impacts that may arise from a Significant Financial Interest are outweighed by interests of scientific progress, technology transfer or the public health and welfare.

Reporting to the Appropriate Agency. The Institute will provide initial, annual (i.e., ongoing) and revised FCOI reports to the appropriate agency, including all reporting elements required by 42 CFR § 50.605(b), as follows: (i) prior to the expenditure of funds; (ii) within 60 days of identification, for a Researcher who is newly participating in the Agency-funded Research; (iii) within 60 days for new, or newly identified, FCOIs for existing Researchers; (iv) at least annually (at the same time as when the Institute is required to submit the annual progress report, multi-year progress report, if applicable, or at the time of extension) to provide the status of the FCOI and any changes to the management plan, if applicable, until the completion of the research; and (v) following a retrospective review to update a previously submitted report, if appropriate.

The Institute will notify the appropriate agency promptly and submit a mitigation report if Bias is found with the design, conduct, or reporting of Agency-funded Research. The Institute's report will include the key elements documented in any retrospective review (for PHS awards,) a description of the impact of the Bias on the research, and the Institute's plan of action or actions taken to eliminate or mitigate the effect of the Bias.

If the failure of a Researcher to comply with this policy or an FCOI management plan appears to have Biased the design, conduct or reporting of the Agency-funded Research, the Institute will promptly notify the appropriate agency of the corrective action taken or to be taken.

The Institute will inform the NSF's Office of the General Counsel via the NSF's electronic system if the Institute finds that an FCOI exists, that the Institute is unable to satisfactorily manage it, and that research will proceed without the imposition of conditions or restrictions.

Maintenance of Records. All FCOI-related records will be retained for at least three years from the date the final expenditures report is submitted to the appropriate agency or, where applicable, from other dates specified in 45 CFR § 75.361. For NSF Agency-funded Research, the Institute will maintain records of all financial disclosures and of all actions taken to resolve FCOIs for at least three years beyond the termination or completion of the grant to which they relate, or until the resolution of any NSF action involving those records, whichever is longer.

Retrospective Reviews (PHS-funded Research). Whenever an FCOI is not identified or managed in a timely manner, including failure by the Researcher to disclose a Significant Financial Interest that is determined by the Institute to constitute an FCOI; failure by the Institute to review or manage an FCOI; or failure by the Researcher to comply with an FCOI management plan, the Institute will, within 120 days of the Institute's determination of noncompliance, complete a retrospective review of the Researcher's activities and the Agency-funded Research to determine whether any Agency-funded Research, or portion thereof, conducted during the time period of the noncompliance was Biased in the design, conduct or reporting of the research. The Institute will document the retrospective review, including all documentation elements set out in 42 CFR § 50.605(a)(3)(ii)(B), and update the previously submitted FCOI report, specifying the actions that will be taken to manage the FCOI going forward. If Bias is found, the Institute will submit a mitigation report, as described above and in 42 CFR § 50.605(a)(3)(iii).

Subrecipient Requirements. When proposed Agency-funded Research is to be carried out through a subrecipient, the Institute will incorporate as part of a written agreement with the subrecipient provisions that establish whether this policy or that of the subrecipient will apply to the subrecipient's researchers, as well as the timeframes within which the subrecipient must provide any information necessary to ensure that the Institute is able to meet any reporting obligations to the appropriate agency.

Public Accessibility. This policy will be made publicly available on www.stowers.org. In addition, the Institute will provide public accessibility, via written response to any requestor within five business days of a request, to information concerning any Significant Financial Interest disclosed to the Institute that meets the following three criteria: (i) the Significant Financial Interest was disclosed and is still held or being received by Senior/Key Personnel, (ii) the Institute has determined that the Significant Financial Interest is related to Agency-funded Research, and (iii) the Institute has determined that the Significant Financial Interest is a FCOI. The information that the Institute must make available to the requestor includes, at a minimum, the information required by 42 CFR § 50.605(a)(5).