

 All Users of SGC Facilities / Legal •  Effective Date: Mar-01-2002  Print

Scope

This Policy on Conflicts of Interest in Research applies to members of the nonprofit organizations within the Stowers Group of Companies ("SGC" and "SGC Organizations"), including Stowers Institute for Medical Research ("SIMR") and Stowers Resource Management Inc. ("SRM"), and to individuals who make substantial use of a SGC Organization's facilities, such as independent contractors, visiting scientists, postdoctoral fellows and approved visitors (collectively, "Covered Individuals").

Purpose

The SGC is committed to conducting its scientific research and other activities 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 or other interests by those Covered Individuals who engage in scientific research and related activities, determining whether those interests constitute a real or perceived conflict of interest or commitment and if so, addressing the conflict so that the scientific research and related activities are conducted free of bias and consistent with his or her obligations to the SGC.

Policy

Definitions

Bias: circumstances under which a Disclosing Covered Individual would experience (or could appear to experience) impaired professional judgment or objectivity resulting from a FOCOI, as determined by the Institutional Official.

Core Leaders: Covered Individuals who lead its research support core facilities.

Disclosing Covered Individual: any Covered Individual engaged in activities related to the design, conduct, direct funding, reporting or commercialization of Research or Research results, including *Senior/Key Personnel* and Core Leaders.

Excluded Financial Interest: a Significant Financial or Other Interest does not include the following Financial Interests:

(i) salary, royalties, or other remuneration paid by a SGC Organization to the Disclosing Covered Individual, including travel expenses paid for or reimbursed by the SGC Organization;

(ii) income from investment vehicles such as mutual funds and retirement accounts, as long as the Disclosing Covered Individual does not directly control the investment decisions made by the investment managers within these funds or accounts; or

(iii) 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 federal, state or local agency within the U.S.; a U.S. institution of higher education as defined at 20 USC § 1001(a); or a U.S. academic teaching hospital, medical center or research institute that is affiliated with an institution of higher education (such as Howard Hughes Medical Institute and Cold Spring Harbor Laboratory.)

Federal Agency: the Public Health Service ("PHS") (National Institutes of Health ("NIH")), the National Science Foundation ("NSF") and any other federal agency that applies the PHS Rule.

Federal Agency-funded Research: Research funded by a Federal Agency.

Financial or Other Conflict of Interest (FOCOI): any situation in which a Significant Financial or Other Interest of a Disclosing Covered Individual (or a member of his or her Family) has the potential to result in (or could appear to result in) Bias or the potential to interfere with or compromise (or could appear to interfere with or compromise) the Disclosing Covered Individual's ability to fulfill his or her obligations to a SGC Organization, as determined by the Institutional Official.

Financial Interest: anything of monetary value, including: (i) salary or other payments for services (e.g., consulting fees, honoraria, paid authorship); (ii) equity interests (e.g., stocks, stock options or other ownership interests); (iii) intellectual property rights (e.g., patents, copyrights,) upon receipt of income related to those rights and interests; and (iv) reimbursed or sponsored travel.

Immediate Family: a Disclosing Covered Individual's spouse, the Disclosing Covered Individual's children, father, mother, sisters and brothers, and their respective spouses, and other persons living in the same household or financially dependent upon the Disclosing Covered Individual.

Institutional Official: the SGC General Counsel or his or her designee.

Other Interest: any activity, whether or not it involves a Financial Interest, which (i) involves an outside employment activity (as defined in the Policy on Outside Employment (131HR)) or (ii) involves any joint or collaborative research with one or more third parties but excluding those conducted pursuant to a written agreement approved by the President and CEO of SIMR or his or her designee.

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: SGC scientific research activities, including research support core facilities that support, advance or otherwise contribute to those activities, regardless of whether those activities are externally or internally funded.

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

Significant Financial or Other Interest: a Financial Interest or Other Interest that (i) is held or received, directly or indirectly, by a Disclosing Covered Individual and/or his or her Family members in, from or with a third party, (ii) is related (or could appear to be related) to the Disclosing Covered Individual's responsibilities to a SGC Organization or overlaps (or could appear to overlap) with the scope of a Federal Agency award, and (iii) is not an Excluded Financial Interest. A Significant Financial or Other Interest will include a Significant Financial Interest as defined in 42 CFR § 50.603.

Disclosure of Financial or Other Interests

In order to identify and manage FOCIs, each Disclosing Covered Individual is required to submit a disclosure statement to the Institutional Official using the applicable form (i) on or before the date the Disclosing Covered Individual is hired, appointed or otherwise becomes associated with a SGC Organization, (ii) annually thereafter, upon solicitation by the Institutional Official, (iii) prior to the Disclosing Covered Individual's submission of a proposal for funding by a Federal Agency, and (iv) within 30 days of any material change in the information disclosed or acquisition of a new Significant Financial or Other Interest.

Review of Significant Financial or Other Interest Disclosures

The Institutional Official will review the submitted the disclosure statement and determine whether a FOCOI exists and whether additional information is required from the Disclosing Covered Individual. The review will take into account the nature and extent of (i) the Significant Financial or Other Interest(s), (ii) the activities conducted by a Disclosing Covered Individual which could affect the Significant Financial or Other Interest(s), and (iii) the Disclosing Covered Individual's role in those activities. The review will also determine whether the Significant Financial or Other Interest(s) are related to Federal Agency-funded Research (i.e., the Significant Financial or Other Interest(s) could be affected by the Federal Agency-funded Research or is in an entity whose Financial Interest could be affected by the Federal Agency-funded Research.) The Institutional Official will review and, if necessary, implement a management plan (discussed below) within 60 days of submission of the disclosure statement or when the Institutional Official otherwise identifies a Significant Financial or Other Interest.

Management of FOCIs

If a FOCOI is determined to exist, the Institutional Official will take appropriate action to manage a FOCOI, including, if necessary, requiring the Disclosing Covered Individual to comply with a management plan, to ensure that (i) the FOCOI will be mitigated or eliminated, (ii) the conduct of the Disclosing Covered Individual's activities will be free from Bias and will be consistent with his or her obligations to a SGC Organization and its interests, and (iii) the safety or validity of Research will not be compromised, in particular Federal Agency-funded Research consistent with the requirements of 42 CFR § 50.605(a). The Institutional Official will monitor the Disclosing Covered Individual's compliance with a required management plan on an ongoing basis, at a minimum until the completion of any Federal Agency-funded Research. For NSF-Federal Agency-funded Research, the Institutional Official may allow the research to go forward without imposing such conditions or restrictions if the Institutional Official 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 or Other Interest are outweighed by interests of scientific progress, technology transfer or the public health and welfare.

Training

Disclosing Covered Individuals must complete FOCOI training (i) immediately after he or she is hired or appointed by a

SGC Organization or otherwise becomes associated with a SGC Organization, (ii) prior to engaging in Federal Agency-funded Research, (iii) immediately after this policy is revised in any manner that affects the requirements of Disclosing Covered Individuals or if he or she violates a management plan or otherwise fails to comply with this policy, and (iv) no less often than every four years.

Non-compliance

Failure by a Disclosing Covered Individual to comply with this policy, including: (i) failing to submit a required disclosure statement when required; (ii) failing to provide additional information when requested; (iii) knowingly filing an incomplete, erroneous or misleading disclosure statement; or (iv) failing to comply with a FOCOI management plan, may result in disciplinary or other adverse action being taken against the Disclosing Covered Individual. Such action could result in a formal reprimand, non-renewal of appointment, or termination of employment, appointment or other association with a SGC Organization, in addition to any enforcement action mandated by a Federal Agency, if applicable to the Disclosing Covered Individual's activities.

For Federal Agency-funded Research, the Institutional Official will, within 120 days of the Institutional Official's determination of noncompliance by the Disclosing Covered Individual or a failure by the Institutional Official to review or manage a FOCOI, complete and document a retrospective review of the Disclosing Covered Individual's activities and the Federal Agency-funded Research to determine whether any Federal 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 Institutional Official 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 FOCOI report (as discussed below), specifying the actions that will be taken to manage the FOCOI going forward.

Reporting to the Appropriate Federal Agency

For Federal Agency-funded Research, the Institutional Official will provide the following reports, notices and other communications to the appropriate Federal Agencies:

- initial, annual (i.e., ongoing) and revised FOCOI reports, 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 Disclosing Covered Individual who is newly participating in the Federal Agency-funded Research; (iii) within 60 days for new, or newly identified, FOCOIs for existing Disclosing Covered Individuals; (iv) at least annually (at the same time as when the annual progress report or multi-year progress report, if applicable, is required to be submitted, or at the time of extension) to provide the status of the FOCOI 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.
- prompt notice and a mitigation report (in compliance with 42 CFR § 50.605(a)(3)(iii)) for any identified Bias or in the event a Disclosing Covered Individual's failure to comply with this policy or a FOCOI management plan appears to have Biased the design, conduct or reporting of the research, which 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 plan of action or actions taken to eliminate, correct or mitigate the effect of the Bias.
- Informing of the NSF's Office of the General Counsel via the NSF's electronic system if a FOCOI is determined to exist and which the Institutional Official is unable to satisfactorily manage, and that research will proceed without the imposition of conditions or restrictions.

Confidentiality

To the extent permitted by this policy and applicable law, the disclosure statements and related records and information submitted by a Disclosing Covered Individual pursuant to this policy will be maintained as confidential.

Subrecipient Requirements

When proposed Federal Agency-funded Research is to be carried out through a subrecipient, the relevant SGC Organization 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 SGC Organization is able to meet any reporting obligations to the appropriate agency.

Public Accessibility

The Institutional Official will make this policy available via a publicly accessible Web site and provide public accessibility, via written response to any requestor within five business days of a request, to information concerning any disclosed Significant Financial or Other Interest that meets the following three criteria, as determined by Institutional Official: (i) the Significant Financial or Other Interest was disclosed and is still held or being received by Senior/Key Personnel, (ii)

the Institutional Official has determined that the Significant Financial or Other Interest is related to Federal Agency-funded Research, and (iii) the Institutional Official has determined that the Significant Financial or Other Interest is a FOCO. The information that must be made available to the requestor includes, at a minimum, the information required by 42 CFR § 50.605(a)(5).