

Policy on Financial Conflict of Interest for Externally Sponsored Projects

Purpose

Southern California University of Health Sciences is committed to promoting objectivity in research and teaching. The purpose of this policy is to ensure there is no reasonable expectation that the design, conduct, or reporting of research or other projects funded by external sponsors will be biased by any conflicting financial interest. The policy establishes a written and enforced administrative process to identify and to manage, reduce or eliminate conflicting interests with respect to all externally sponsored projects. The policy also supports Southern California University of Health Sciences' institutional compliance with the Public Health Service regulations (42 CFR Part 50, Subpart F¹) and the provisions of the National Institutes of Health ².

Scope

The policy applies to all Southern California University of Health Sciences "Investigators", as defined below, who are funded by or are responsible for the design, conduct, reporting or approval of any externally sponsored projects.

The policy also applies to subgrantees, contractors, or collaborators of Southern California University of Health Sciences involved in an externally sponsored project unless individuals can provide written assurance to the Director of Sponsored Projects that they are subject to a similar financial conflict of interest policy.

Definitions³

¹ http://grants.nih.gov/grants/policy/coi/fcoi_final_rule.pdf

² [Financial Conflict of Interest | grants.nih.gov](http://grants.nih.gov/grants/policy/coi/fcoi_final_rule.pdf)

³ Most definitions are derived from Public Health Service regulations 42 CFR Part 50, Subpart (reference 2).

Conflict of Interest (Financial) exists when significant financial interest may affect the design, conduct, or reporting of the externally sponsored project. This includes situations where financial considerations may compromise or have the appearance of compromising faculty or staff member's professional judgment in conducting or reporting research, impacting the collection, analysis, and interpretation of data, hiring of staff, procurement of materials, sharing of results, choice of protocol, involvement of human subjects and application of statistical methods.

"Investigator" means the principal investigator, any co-principal investigators, and any senior/key personnel. The term also includes University faculty and staff who have independent responsibility for designing, conducting, or reporting research, regardless of title or position and may include, for example, post-doctoral students paid on research grants, collaborators, or consultants. For financial interest disclosure purposes, the term also includes the Investigator's family members.

Family Member means the faculty or staff member's spouse or dependent children.

Research means a systematic investigation designed to develop or contribute to knowledge.

Significant Financial Interest means anything of monetary value, including but not limited to, salary or other payments for services (e.g., consulting fees or honoraria); equity interests (e.g., stocks, stock options or other ownership interests); and intellectual property rights (e.g., patents, copyrights and royalties from such rights). Examples of Significant Financial Interest might include employment of a spouse by the potential sponsor or a consulting arrangement with a company that might benefit financially from the sponsored project.

The term does not include: (1) salary, royalties, or other remuneration Southern California University of Health Sciences;

(2) income from seminars, lectures, or teaching engagements sponsored by public or nonprofit entities;

(3) income from service on advisory committees or review panels for public or nonprofit entities;

(4) an equity interest that when aggregated for the faculty or staff member and his or her family members meets both of the following tests:

- i. does not exceed \$5,000 in value as determined through reference to public prices or other reasonable measures of fair market value for a publicly traded entity, and
- ii. does not represent any ownership interest in any single entity that is non publicly traded; or

(5) salary, royalties or other payments that are not from Southern California University of Health Sciences and that when aggregated for the faculty or staff member and his or her family members over the next twelve months, are not expected to exceed \$5,000.

Sponsored Project means any externally funded activity which is subject to an agreement that is binding on the University and that includes any of the following conditions:

- (1) it commits the University to a specific plan of research or scholarly inquiry;
- (2) it makes a specific commitment regarding the level of personnel effort, items of output, or achievement of specific performance targets;
- (3) it requires both adherence to a line item budget and either a detailed fiscal report or an external audit of the project;
- (4) it requires that any unexpended funds be returned to the sponsor at the end of the project period; or
- (5) it provides for the disposition of either tangible property (e.g., equipment, records, or technical reports) or intangible property (e.g., patents or copyrights) that may result from the activity.

Enforcement and Noncompliance

No employee (faculty or staff), officer, board member, or agent of Southern California University of Health Sciences will participate in the selection, award, or administration of a contract supported by a Federal award if he or she has a real or apparent conflict of interest. Such a conflict of interest would arise when the employee, officer, board member or agent, any member of his or her immediate family, his or her partner, or an organization which employs or is about to employ any of the parties indicated herein, has a financial or other interest (as

defined above) in or a tangible personal benefit from a firm considered for a contract.

Condition under which outside activities, relationship, or financial interests are improper would include if the person has, directly or indirectly, through business, investment, or family:

- a. An ownership or investment interest in any entity with which Southern California University of Health Sciences has a transaction or arrangement,
- b. A compensation arrangement with Southern California University of Health Sciences or with any entity or individual with which Southern California University of Health Sciences has a transaction or arrangement, or
- c. A potential ownership or investment interest in, or compensation arrangement with, any entity or individual with which Southern California University of Health Sciences is negotiating a transaction or arrangement.

The officers, board members, employees, and agents of Southern California University of Health Sciences must neither solicit nor accept gratuities, favors, or anything of monetary value from contractors or parties to subcontracts, unless the financial interest is not substantial, or the gift is an unsolicited item of nominal value.

All employees and Board members are required to complete an annual conflict of interest questionnaire which is submitted to the President's Office. In connection with any actual or possible conflict of interest, an interested person must disclose the existence of the financial interest and be given the opportunity to disclose all material facts to the Board Chairperson or CEO. Any employee, officer, board member, or agent may recuse himself or herself at any time from involvement in any decision or discussion in which the individual believes he or she has or may have a conflict of interest, without going through the process for determining whether a conflict of interest exists. The Board members or CEO shall decide if a conflict of interest exists. Disciplinary actions will be applied for violations of such standards by officers, employees, or agents of Southern California University of Health Sciences. If the Board or CEO has reasonable cause to believe a member has failed to disclose actual or possible conflicts of interest, it shall inform the individual of the basis for such belief and afford the member an opportunity to explain the alleged failure to disclose. If, after hearing the individual's response and after making further investigation as warranted by the circumstances, the Board or CEO determines

the member has failed to disclose an actual or possible conflict of interest, it shall take appropriate disciplinary and corrective action, including possible termination or removal from board.

Organizational Conflicts of Interest

Because of relationships with a parent company, affiliate, or subsidiary organization, Southern California University of Health Sciences is unable or appears to be unable to be impartial in conducting a procurement action involving a related organization and will not procure with those organizations.

It is the policy of Southern California University of Health Sciences to comply with the requirements of 42 CFR 50, Subpart F, "Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is Sought." The requirements promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct, or reporting of research funded under PHS grants or cooperative agreements will be free from bias by any conflicting financial interest of an Investigator, defined as the PD/PI and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research funded by PHS, or proposed for such funding, which may include, for example, collaborators or consultants.

Research Programs Conflicts of Interest

Southern California University of Health Sciences will be in compliance with the following requirements of 42 CFR 50, Subpart F, including:

1. There is in effect an up-to-date, written and enforced administrative process to identify and manage Financial Conflicts of Interest (FCOI) with respect to all research projects for which NIH funding is sought or received;
2. Southern California University of Health Sciences shall promote and enforce Investigator compliance with the regulation's requirements including those pertaining to disclosure of Significant Financial Interests;
3. Southern California University of Health Sciences shall identify and manage FCOIs and provide initial and ongoing FCOI reports to the NIH consistent with this subpart;

4. When requested, the Institution will promptly make information available to the NIH/HHS relating to any Investigator disclosure of financial interests and the Institution's review of, and response to, such disclosure, whether or not the disclosure resulted in the Institution's determination of an FCOI;
5. Southern California University of Health Sciences shall fully comply with the requirements of the regulation.

When Southern California University of Health Sciences determines that an FCOI exists (see #3 above), Southern California University of Health Sciences must report to the NIH awarding IC through the submission of an initial and annual FCOI report using the eRA Commons FCOI Module. Southern California University of Health Sciences will make certain information available concerning identified FCOI held by senior/key personnel as defined in the regulation via a publicly accessible Web site or by a written response to any requestor within five business days of a request, and update such information as specified in the regulation.

The annual FCOI report must be submitted to the NIH through the eRA Commons FCOI Module each year within a competitive segment or until Southern California University of Health Sciences reports that the FCOI no longer exists.

Southern California University of Health Sciences will incorporate, as part of a written agreement with a subrecipient, terms that establish whether the FCOI policy of Southern California University of Health Sciences or that of the subrecipient will apply to subrecipient Investigators and include time periods to meet disclosure and/or FCOI reporting requirements. Subrecipient Institutions who rely on their FCOI policy must report identified Financial Conflicts of Interest to Southern California University of Health Sciences in sufficient time to allow Southern California University of Health Sciences to report the FCOI to the NIH to meet its reporting obligations.

Southern California University of Health Sciences will require each Investigator (including subrecipient Investigators, if applicable) to complete training prior to engaging in NIH-

supported research and at least every four years, and immediately under the designated circumstances:

1. Institutional FCOI policies change in a manner that affects Investigator requirements
2. An Investigator is new to an Institution
3. An Institution finds an Investigator noncompliant with the Institution's FCOI policy or management plan.