

Policy on Financial Conflict of Interest for Externally Sponsored Projects¹

Purpose

Santa Clara University is committed to promoting objectivity in teaching and research. 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 Santa Clara University's institutional compliance with the Public Health Service regulations (42 CFR Part 50, Subpart F²) and the provisions of the National Science Foundation (Grant Policy Manual § 150³).

Scope

The policy applies to all Santa Clara University faculty and staff who are funded by or are responsible for the design, conduct, reporting or approval of any externally sponsored project⁴ at Santa Clara University.

The policy also applies to subgrantees, contractors, or collaborators of Santa Clara University 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.

The policy shall be part of the Conflict of Interest policies in the Staff Policy Manual (Policy 304) and the Faculty Handbook (Section 3.6.5).

Policy

Any Santa Clara University faculty or staff member who is funded by or is responsible for the design, conduct, reporting or approval of any externally sponsored project is required to disclose all known Significant Financial Interests and those of his or her family members that would reasonably appear to be affected by the project.

¹ In drafting this document, similar policies were reviewed from Creighton University, Stanford University, University of Notre Dame, Georgetown University, University of Chicago, Loyola University Chicago, and Loyola Marymount University. Creighton University policies served as a template for this document.

² http://grants.nih.gov/grants/compliance/42_CFR_50_Subpart_F.htm

³ http://www.nsf.gov/pubs/manuals/gpm05_131/gpm5.jsp#510

⁴ This policy does not apply to Small Business Innovation Research (SBIR) Program, the extramural research program for small business that was established by the Awarding Components of the Public Health Service and certain other Federal agencies under Pub. L. 97-219, the Small Business Innovation Development Act, as amended. The SBIR Program includes the Small Business Technology Transfer (STTR) Program, which was established by Pub. L. 102-564.

Enforcement and Noncompliance

The Associate Provost for Research Initiatives and Director of Sponsored Projects are responsible for enforcement of the policy. Examples of noncompliance with this policy include, but are not limited to, failure to submit a disclosure form, intentionally filing an incomplete, erroneous, or misleading disclosure form, or failing to provide any additional information requested by the Director of Sponsored Projects or the Associate Provost for Research Initiatives. Failure to comply with this policy will result in the notification of the sponsor (Procedure Section G) and immediate suspension of all sponsored project funds. In addition, noncompliance may result in disciplinary action consistent with and subject to sections of the Staff Policy Manual and the *Faculty Handbook* that are applicable to the employment of the faculty or staff member. In particular, noncompliance is subject to the Policy on Misconduct in Research (*Faculty Handbook*, Appendix H).

Definitions⁵

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.

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. The term encompasses basic and applied research and product development.

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. Other examples are listed in Appendix A.

The term does *not* include:

- (1) salary, royalties, or other remuneration from Santa Clara University;
- (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;

⁵ Most definitions are derived from Public Health Service regulations 42 CFR Part 50, Subpart (reference 2).

- (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 \$10,000 in value as determined through reference to public prices or other reasonable measures of fair market value, and
 - ii. does not represent more than a five percent ownership interest in any single entity; or
- (6) salary, royalties or other payments that are not from Santa Clara University 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 \$10,000.

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.

Appendix A

Examples of Significant Financial Interests

The following are examples of Significant Financial Interests that must be reported on the Statement of Significant Financial Interests Form. These examples are neither exclusive nor exhaustive of the types of significant financial interests that may be reportable under the Policy on Financial Conflict of Interest for Externally Sponsored Projects.

- Payments (e.g., stipends, honoraria) from a sponsor, directly or indirectly, for speaking engagements when the faculty or staff member knows the source of the funding for the speaking fee. In those instances where the speaking fee is received indirectly from the sponsor, the faculty or staff member should disclose who determines the content, who selects

the speakers and other factors that may assist in determining whether or not a conflict of interest exists.

- Income from service on the advisory board or scientific review panel for a for-profit pharmaceutical company that exceeds \$10,000 for the previous calendar year or is expected to exceed \$10,000 over the next 12 months from the date of completing the Disclosure Form.
- Consulting fees from any sponsor (excluding service on an advisory board or scientific review panel of a government or non-profit company) that exceeds \$10,000 for the previous calendar year or is expected to exceed \$10,000 over the next 12 months from the date of completing the Disclosure Form.
- A family member's direct ownership of stock in a publicly traded company valued at over \$10,000 that may or may not be affected by the project.
- Any payment incentives (money, gifts, other items of value) above and beyond the actual costs of enrollment, conduct of the research and reporting of the results, such as finders fees, recruitment bonuses, enrollment bonus for reaching an accrual goal.
- Payments for protocol or study design that exceed \$10,000 in the previous calendar year or that are expected to exceed \$10,000 over the next 12 months.
- A right or expectation of obtaining a proprietary interest related to the project or related to any test article or device that will be used in the project, including any proprietary interests that the faculty or staff member may assign to any entity, including Santa Clara University.
- Serving as an officer or director (whether or not paid for such service) with any entity providing funds or other support to the project or in any entity that may be affected (benefited or harmed) by the results of the project (i.e., competitor, customer, collaborator or affiliate of a commercial sponsor).
- Planning to use project funds to purchase items or services from an entity in which the faculty or staff member or a family member has an interest (stock, stock options, employment, or partnership).
- Holding a 10% partnership interest (valued at \$5,000) in an entity that may be impacted (detriment or benefit) by the proposed project.