

Policy on Financial Conflict of Interest for Externally Sponsored Projects
Revised August 8, 2012

Procedures

A. Disclosure of Potential Conflicts of Interest

The Sponsored Projects Office shall provide all faculty and staff who are funded by or are responsible for the design, conduct, reporting or approval of any externally sponsored project with a copy of this policy and advise them of their reporting obligations. The procedures for disclosure of Significant Financial Interests are as follows:

1. *Current Projects.* Faculty and staff participating in currently funded projects shall complete and submit a “Disclosure of Financial Relationship for Sponsored Projects” (Disclosure Form), to the Director of Sponsored Projects (Director). A new Disclosure Form must be completed every year even if there are no changes.
2. *Proposals for New Projects.* All faculty and staff shall complete and submit a new Disclosure Form or complete and submit an update to a current Disclosure Form to the Director prior to the time the project is submitted to the external sponsor. Grant application(s) will not be approved by Sponsored Projects until a Disclosure Form for each current faculty and staff involved in the project has been submitted.
3. *Faculty and Staff added to an Existing Project.* Faculty and staff added to an existing project must complete and submit a Disclosure Form to the Director before they can be added to the project. No one shall be added to the project until the Disclosure Form has been reviewed pursuant to these procedures. For new staff positions funded by a sponsored project, the Disclosure Form must be completed and reviewed *before* there is an offer of employment. A Disclosure Form must be completed annually.
4. *New or Additional Financial Interests.* If any faculty or staff member or family member obtains a new or additional Significant Financial Interest, the faculty or staff member must submit an updated Disclosure Form to the Director within 30 days of acquiring the new or additional Significant Financial Interest.
5. *Annual Disclosure.* Faculty or staff members working on an active externally funded project shall annually submit a Disclosure Form to the Director on or before the 31st day of January. The annual Disclosure Form shall include Significant Financial Interests obtained during the previous calendar year (January 1 through December 31) or that are expected to exceed \$5,000 during the next 12 month period.

B. Review Process

1. *Initial Review by the Director.* The Director will review each Disclosure Form to ensure that it has been properly filled out and signed by the faculty or staff member to determine the existence of any Significant Financial Interest.

If the Director determines that no Significant Financial Interest exists as outlined in these procedures, the Director shall notify the faculty or staff member in writing within 15 working days of receiving the disclosure and include this correspondence in the project file. In addition, the Director shall notify the external sponsor according to the sponsor's policies.

If the Director determines that a Significant Financial Interest may exist, then the Disclosure Form shall be referred to the Associate Provost for Research and Faculty Affairs within 5 working days of receiving the disclosure. If the project involves human subjects research, the Director shall give a copy of the Disclosure Form to the Human Subjects Committee. The Director shall notify the faculty or staff member that the matter has been referred to the Associate Provost for Research and Faculty Affairs (and Human Subjects Committee, where applicable) for review and that no project funds will be released until a final determination has been made.

2. *Review by Associate Provost for Research and Faculty Affairs.* The Associate Provost shall review (and where necessary investigate) all information contained in the Disclosure Form. If the Associate Provost is not available, the Vice Provost for Academic Affairs will conduct the review and manage the process.

During the review, the Associate Provost may consider one or more of the following factors in determining the existence of a potential or actual financial Conflict of Interest (Department of Health and Human Services guidance 69 F.R. 26393-26397; May 12, 2004)¹:

- How is the research supported or financed?
- Where and by whom was the study designed?
- Where and by whom will the resulting data be analyzed?
- What interests are created by the financial relationships involved in the situation?
- Do individuals or institutions receive any compensation that may be affected by the study outcome?
- Do individuals or institutions involved in the research:
 - have any proprietary interests in the product, including patents, trademarks, copyrights, or licensing agreements?
 - have an equity interest in the research sponsor and, if so, is the sponsor a publicly held company or non-publicly held company?

¹ <http://www.gpo.gov/fdsys/pkg/FR-2004-05-12/pdf/04-10849.pdf>

- receive significant payments of other sorts? (e.g., grants, compensation in the form of equipment, retainers for ongoing consultation, or honoraria)
 - receive payment per participant or incentive payments, and are those payments reasonable?
 - Given the financial relationships involved, is the institution an appropriate site for the research?
 - How should financial relationships that potentially create a conflict of interest be managed?
 - Would the rights and welfare of human subjects be better protected by any or a combination of the following:
 - Reduction of the financial interest?
 - Disclosure of the financial interest to prospective subjects?
 - Separation of responsibilities for financial decisions and research decisions?
 - Additional oversight or monitoring of the research?
 - An independent data and safety monitoring committee or similar monitoring body?
 - Modification of role(s) of particular research staff or changes in location for certain research activities, e.g., a change of the person who seeks consent, or a change of investigator?
 - Elimination of the financial interest?
3. *Review by Conflict of Interest Review Committee.* If the Associate Provost determines that a Conflict of Interest may exist, he or she shall appoint a Conflict of Interest Review Committee to conduct a review of the case and, as necessary, to recommend a resolution plan that places appropriate restrictions to manage, reduce or eliminate the Conflict of Interest. The Committee shall be composed of one member selected by the Research Committee, one member selected by the Faculty (or Staff) Affairs Committee, one member selected by the appropriate Dean, one member selected by the appropriate Department Chair or Supervisor, and one member selected by the Associate Provost. If the project involves human subjects, the Chair of the Human Subjects Committee will be an additional member of the Committee.
4. The Committee should complete its review within 30 working days of Sponsored Projects receiving the disclosure. If additional time is needed, a request can be made to the Associate Provost. After completing its review, the Committee shall make one of the following determinations:
1. No potential or actual Conflict of Interest exists and no further action is necessary.
 2. A potential or actual Conflict of Interest exists and appropriate controls already exist to manage, reduce or eliminate the Conflict of Interest.
 3. A potential or actual Conflict of Interest exists that is not adequately addressed and a resolution plan is prepared to satisfactorily manage, reduce or eliminate the identified conflict of interest so that the faculty or staff member may participate in the research or educational project.

4. A potential or actual Conflict of Interest exists and it is not possible to implement a plan to satisfactorily manage, reduce or eliminate the identified conflict of interest in such a manner as to allow the faculty or staff member to participate in the research or educational project.

As necessary, the Committee will recommend a resolution plan that may include controls not limited to one or more of the following:

- a. Disclosure – disclosure includes, but is not limited to, (i) public disclosure of the significant financial interest(s) in all relevant publications and all presentations (whether or not academic presentations), (ii) disclosure to members of the project and (iii) disclosure to human subjects through informed consent;
- b. Monitoring – appointment of independent reviewer(s) or independent data and safety monitoring committee or similar body to monitor the project. Monitoring may include reviewing abstracts and manuscripts before submission for publication; review of protocols, subject accrual, complications and other issues;
- c. Modification – modification of the project such that the main purpose of the project is not compromised;
- d. Limitation or Disqualification – limitations may include prohibiting the faculty or staff member from (i) serving as the Principal Investigator; (ii) analyzing the data; (iii) selecting or enrolling human subjects; or (iv) any other limitation capable of managing, reducing or eliminating the conflict of interest including disqualifying the faculty or staff member from participating in the project;
- e. Divestiture – allow the faculty or staff member to proceed with the project subject to the sale or disposal of all or a portion of specified financial interests to reduce or eliminate financial conflicts;
- f. Severance of Relationships – requiring the faculty or staff member or his or her family member to sever relationships that create actual or potential conflicts, such as relinquishing a seat on a board of directors or terminating a consulting agreement with an outside entity during the course of the project;
- g. Restrictions on Equity Interests – requiring the faculty or staff member or his or her family member to place stock in escrow until a trigger date specified by the Associate Provost, or requiring options, warrants and similar interests not be exercised without prior written approval of the Associate Provost (and Human Subjects Committee, if human subjects are involved).
- h. Any other conditions or restrictions that will contribute to the management, reduction or elimination of the Conflict of Interest, consistent with applicable policies, regulations and laws.

The Committee will submit to the Associate Provost a summary report including a brief description of its findings, a clear statement of its determination and, as needed, a recommended resolution plan within 30 working days of Sponsored Projects receiving the disclosure. The Associate Provost will review the summary report. If the resolution plan calls for the limitation or disqualification of a faculty or staff member from a project, Human Resources and the Provost will be consulted to ensure that all appropriate University policies and procedures are followed.

The Associate Provost will meet with the faculty or staff member to discuss the determination and resolution plan. After the meeting, the faculty or staff member will receive a letter from the Associate Provost stating the final determination and outlining the final resolution plan. The letter will be dated and sent no longer than 40 working days of Sponsored Projects receiving the disclosure. A copy of the letter will be sent to the Director of Sponsored Projects and retained for at least three years (F. Records Retention).

In the case of National Science Foundation sponsored projects³, when a potential or actual Conflict of Interest exists, but it is determined that the placement of restrictions or conditions will be 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, the Associate Provost may allow the faculty or staff member to participate without placing any conditions or restrictions after the National Science Foundation has been notified of the Associate Provost's decision.

If the faculty or staff member does not agree to comply with the resolution plan, he or she will not be able to continue working on the project and, as necessary, the Director will not allow funds to be expended on the project. A faculty or staff member may appeal the resolution plan as described in section E below.

After the appeal process has concluded or the deadline for an appeal has passed, the Director will then make all necessary notifications to sponsors (section E. Appeal Rights) within 60 working days of Sponsored Projects receiving the disclosure form.

5. *Review of Projects involving Human Subjects Research.* The Significant Financial Interest(s) of a faculty or staff member involved in human subject research may present real or perceived risks to the welfare of human subjects and may require additional review. If the project involves human subjects, then the Conflict of Interest Review Committee will consult with the Human Subjects Committee as part of its review. The Human Subjects Committee may provide suggestions for the resolution plan. After the Conflict of Interest Review Committee has made its determination and, as needed, recommended a resolution plan, the Associate Provost shall ask the Human Subjects Committee to review the final determination and resolution plan. The Human Subjects Committee may accept or decline the determination and resolution plan. The Human Subjects Committee is ultimately responsible for protecting the rights and welfare of

human subjects. If the Human Subjects Committee is not satisfied with the final determination or the resolution plan, it may decide to not to approve the project.

C. Appeal Rights

If the faculty or staff member disagrees with the determination or resolution plan, he or she may appeal by submitting a written request to the Provost for reconsideration along with any supporting materials within 10 working days from date of the determination letter from the Associate Provost (B.4 above). The Provost will review the request and supporting materials and issue a written final determination, which shall not be subject to further appeal, within 10 working days of receiving the appeal. The faculty or staff member shall sign any resolution plan required by the Provost before any funds will be expended under the project(s). A copy of the final determination and signed resolution plan will be sent to the Director of Sponsored Projects and retained for at least three years (see F. Records Retention). The Director will then make all necessary notifications to sponsors.

If the faculty or staff member does not agree to comply with the resolution plan, he or she will not be able to continue working on the project and, as necessary, the Director will not allow funds to be expended on the project.

D. Records Retention

The Director of Sponsored Projects shall retain records of all financial disclosures and all actions taken by Santa Clara University with respect to each conflicting interest as follows:

1. *Public Health Services Funded Projects*: Three years after the date of submission of the final expenditures report or, where applicable, from other dates specific in 45 CFR 74.53 (b)² for different situations;
2. *National Science Foundation Funded Projects*: Three years beyond the termination or completion of the project, or until the resolution of any National Science Foundation action involving those records, whichever is longer; or
3. *All Other Externally Funded Projects*: Three years after the termination or completion of the project.

E. Other Requirements

1. *Public Health Services Certification and Notification*. The appropriate Santa Clara University official shall certify on each Public Health Services funded proposal that:

² http://oma.od.nih.gov/pi/45cfr74_53.pdf

* *Public Health Services includes: [Administration for Children and Families](#) (ACF); [Administration on Aging](#) (AoA); [Agency for Healthcare Research and Quality](#) (AHRQ); [Agency for Toxic Substances and Disease Registry](#) (ATSDR); [Centers for Disease Control and Prevention](#) (CDC); [Centers for Medicare & Medicaid Services](#) (CMS); [Federal Occupational Health](#) (FOH); [Food and Drug Administration](#) (FDA); [Health Resources and Services Administration](#) (HRSA); [Indian Health Service](#) (IHS); [National Institutes of Health](#) (NIH); [Substance Abuse and Mental Health Services Administration](#) (SAMHSA).

- a. there is a written and enforced administrative process to identify, manage, reduce or eliminate conflicting interests;
 - b. prior to the expenditure of any funds, a report will be made to the Public Health Services awarding component of any Conflict of Interest (but not the nature of the interest or details) found by Santa Clara University and assure that the interest has been managed, reduced or eliminated. If any conflicting interest is identified subsequent to the initial report, a report will be made and the Conflict of Interest managed, reduced or eliminated at least on an interim basis, within 60 days of that identification; and
 - c. upon request, make information available to the Department of Health and Human Services regarding all conflicting interests and how those interests have been managed, reduced or eliminated.
2. *National Institute of Health Notification.* Prior to the expenditure of any funds, the Director of Sponsored Projects shall submit a report to the National Institute of Health of any conflicting interest (but not the nature of the interest or other details) found by Santa Clara University and assure that the interest has been managed, reduced or eliminated. If any conflicting interest is identified subsequent to Santa Clara University's initial report, a report will be made and the Conflict of Interest managed, reduced or eliminated, at least on an interim basis, within 60 days of that identification.

a. Contents of Reports

Initial Report:

- Grant/Contract number
- Name of faculty or staff member with Financial Conflict of Interest
- Whether Financial Conflict of Interest was managed, reduced, or eliminated
- Name of the entity with which the faculty or staff member has a Financial Conflict of Interest
- Nature of FCOI, e.g., equity, consulting fees, travel reimbursement, honoraria
- Value of the financial interest \$0-4,999; \$5K-9,999; \$10K-19,999; amts between \$20K-\$100K by increments of \$20K; amts above \$100K by increments of \$50K or statement that a value cannot be readily determined.
- A description how the financial interest relates to PHS-funded research and the basis for the Institution's determination that the financial interest conflicts with such research
- Key elements of the Institution's management plan

Annual report:

- Status of the Financial Conflict of Interest
- Changes to the management plan

b. Public Accessibility

The Financial Conflict of Interest policy must be available on the University website. All Financial Conflict of Interest related to NIH funded grant or contract must be posted on the website prior to expenditure of funds.

c. Financial Conflict Of Interest Training

Faculty and staff members subject to this policy must complete training prior to engaging in research related to any NIH funded grant or contract and at least every four years, and immediately under the following circumstances:

- the Financial Conflict of Interest policy changes in a manner that affects faculty or staff member requirements;
- Faculty or staff member is new to the university; or
- The University finds faculty or staff member noncompliant with the Financial Conflict of Interest policy or management plan.

d. Retrospective Review

The University is required to conduct a retrospective review in cases of non-compliance with the regulation and is required to notify and submit a report to NIH only in cases where Conflict of Interest is found. The report should address the impact of the Conflict of Interest on the research project and the actions the Institution has taken, or will take, to eliminate or mitigate the effect of the Conflict of Interest.

3. ***National Science Foundation Notification.*** The Director of Sponsored Projects shall keep the National Science Foundation Office of the General Counsel appropriately informed if Santa Clara University finds that it is unable to satisfactorily manage a Conflict of Interest under a National Science Foundation sponsored project.