

Policy on Financial Conflict of Interest for Externally Sponsored Projects¹

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), Appendix I, to the Director of Sponsored Projects (Director). A new Disclosure Form must be completed every three years 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. If a Disclosure Form has been completed in the last three years, then only an update to the form is required.
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 \$10,000 during the next 12 month period.

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.

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 Initiatives 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 Initiatives (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 Initiatives.* The Associate Provost shall review (and where necessary investigate) all information contained in the Disclosure Form. If the Associate Provost is not available, the Senior Vice Provost 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)²:

- 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?
 - receive significant payments of other sorts? (e.g., grants, compensation in the form of equipment, retainers for ongoing consultation, or honoraria)

² <http://a257.g.akamaitech.net/7/257/2422/14mar20010800/edocket.access.gpo.gov/2004/04-10849.htm>

- 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.

E. 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.

F. 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)³ 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.

G. 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:
 - a. there is a written and enforced administrative process to identify, manage, reduce or eliminate conflicting interests;

³ http://oma.od.nih.gov/pi/45cfr74_53.pdf

- 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.
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.

Procedures for Sponsored Projects Administration

All staff of the Sponsored Projects Office must also annually complete a Disclosure Form. The staff will be provided with a list of external sponsors so that only information related to such sponsors needs to be disclosed. These forms will be reviewed by the Associate Provost for Research Initiatives and any investigations will follow the procedures outlines for faculty or staff members above. The Associate Provost for Research Initiatives must also complete an annual disclosure form. The Senior Vice Provost will review the forms for the Associate Provost and conduct any investigations following the procedures outlined for faculty or staff members. The Senior Vice Provost must also complete an annual disclosure form. The Provost will review the forms for the Senior Vice Provost and conduct any review following the procedures outlined for faculty and staff members.

Appendix I



Disclosure of Financial Relationship for Sponsored Projects

Name (Print): _____

Date: _____

Type of Personnel

- Investigator Co-Investigator Support Personnel SPO Staff/Administrator
 Sub-grantee Contractor Collaborator

Type of Disclosure

- Full Disclosure (initial or three-year disclosure; all pages must be completed)
 Update with changes (all pages must be completed)
 Update for a new proposal submission
 If a current full disclosure is on file and you have no changes, then you may simply read the following statement and sign below. Only this page (page 1) of the disclosure document needs to be submitted.

I have reviewed my current full disclosure document and there are no changes.

Signed: _____ Dated: _____

- If you have changes to your disclosure or you have not yet completed a disclosure form, then please complete and submit all pages of this document.

Annual Disclosure

- If a current full disclosure is on file and you have no changes, then you may simply read the following statement and sign below. Only this page (page 1) of the disclosure document needs to be submitted.

I have reviewed my current full disclosure document and there are no changes.

Signed: _____ Dated: _____

- If you have changes to your disclosure, then please complete and submit all pages of this document.

This Form shall be completed by all faculty and staff pursuant to the Policy on Financial Conflict of Interest for Externally Sponsored Projects.

Section A. Financial Interests and Relationships

Report all financial interests and relationships currently held, or held within the past 12 months (or during the previous calendar year for annual disclosures), unless otherwise stated, indicating the amount of the financial interest or relationship and the entity or organization. This form must be updated with 30 days of acquiring any new or additional financial interests or relationships.

1. Payment for Services. Any and all salaries and other payments for services (e.g., consulting fees, honoraria, study design, management position, independent contractor, service on advisory committees or review panels of for-profit entities, board membership of for-profit entities, seminars, lectures or teaching engagements for for-profit entities), when totaled together exceeded \$10,000 during the previous 12 months or are expected to exceed \$10,000 over the next 12 months.

Yes No

If Yes, note amount with explanation of source:

2. Equity (Ownership) Interests. Any and all equity interests or ownership interests (e.g., stock, stock options, partner) in entities related to the research activity that when totaled together exceed \$10,000 in value or represent more than 5% equity (ownership) interest. EXCLUDES INTERESTS IN DIVERSIFIED MUTUAL FUNDS.

Yes No

If Yes, note amount with explanation of source:

3. Other Financial Interests or Relationships. Any and all loans, payments, gifts, in-kind contributions or similar financial interests or relationships with research related entities.

Yes No

If Yes, note amount with explanation of source:

4. Incentives. If involved in any research activity will you receive any money, gift or anything of monetary value above and beyond the actual costs of enrollment, conduct of the research, and reporting on the results, including, but not limited to, finders fees, referral fees, recruitment bonuses, an enrollment bonus for reaching an accrual goal or similar types of payments?

Yes No

If Yes, note amount with explanation of source:

5. Other. Any other interests or relationships (including volunteer services) that might constitute a conflict of interest or an appearance of conflict of interest in connection with the research project.

Yes No

If Yes, note amount with explanation of source:

Section B. Declaration

I, my spouse and/or my dependent children **have** a significant financial interest with an entity (or its affiliate) that is providing funds or other support for any research and/or education project, or that may be affected by the research and/or education project as noted in Section A above.

I, my spouse and/or my dependent children **do not have** a significant financial interest with an entity (or its affiliate) that is providing funds or other support for any research and/or education project, or that may be affected by the research and/or education project.

Section C. Attestation

I affirm that I:

- have read the Policy on Financial Conflict of Interest for Externally Sponsored Projects and agree to abide by its terms.
- will update this Disclosure Form on an annual basis or as any new reportable significant financial interest arises.
- will comply with any resolution plan to manage, reduce or eliminate any actual or potential financial conflict of interest before conducting any research or educational activity where a conflict of interest has been identified according to Santa Clara's Policy on Financial Conflict of Interest for Externally Sponsored Projects.

Signed: _____ Dated: _____
(Original Signature required)

Please submit the completed and signed form to the Director of Sponsored Projects.