



2.7.3 Financial Conflicts of Interest in Externally Funded Research

1. Introduction

The University of San Diego's research activities are enhanced by the sustained, active interaction of members of the University community with business, government, not-for-profit organizations, professional societies, academic institutions, and other individuals and entities. The University also recognizes that members of the University community participate actively in community, political, religious, and cultural activities and institutions, and other personal and economic endeavors.

These interactions inherently create the potential for conflicts of interest in which the external activities, income or other interests of a University community member may create real or perceived conflicts of interest with respect to the individual's research activities for or at the University. The University is committed to overseeing the conduct of research in a manner that ensures the integrity of the research process and that maintains the trust of the public and its external sponsors. To that end, the University takes appropriate steps to ensure the appropriate disclosure, review and management of conflicts of interests of those who are responsible for the design, conduct, reporting or direct administration of University research activities.

This document sets forth the University's policy on the avoidance, disclosure, management and resolution of financial conflicts of interest regarding externally-funded research at the University. This policy also includes the requirements necessary to conform to applicable federal law and regulations regarding financial conflicts of interest in federally-funded research, including but not necessarily limited to the conflict of interest regulations issued by the United States Department of Health and Human Services Public Health Service ("PHS"), 42 CFR Part 50. Except where specifically indicated, the University has adopted the provisions in this policy for all externally-funded research, whether funded by PHS or another external source.

2. Key Definitions

- a. **Externally-Funded Research.** Externally-Funded Research means funding, or applications or proposals therefore, for research, research training, or activities related to that research or training, that may be provided through: external grants, cooperative agreements, or contracts or subgrants or subcontracts under those external funding instruments; or salary or other payments under external grants, cooperative agreements or contracts.

- b. **Family Member.** A Family Member includes the Investigator's spouse, registered domestic partner, and dependent children of the Investigator or the Investigator's registered domestic partner.
- c. **Financial Conflict of Interest.** A Financial Conflict of Interest means a Significant Financial Interest that could directly and significantly affect the design, conduct, or reporting of Externally-Funded Research.
- d. **Financial Interest.** Financial Interest means anything of monetary value, whether or not the value is readily ascertainable.
- e. **Institutional Responsibilities.** Institutional Responsibilities means an Investigator's professional responsibilities on behalf of the University, examples of which include teaching, research, service activities, and institutional committee memberships.
- f. **Investigator.** Investigator means the project director or principal investigator and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of any Externally-Funded Research. Collaborators, contractors, and consultants who have any responsibilities of Investigators are considered Investigators for the purposes of this policy.
- g. **Significant Financial Interest.** A Significant Financial Interest means:
 - (i) A Financial Interest consisting of one or more of the following interests of the Investigator (and those of the Investigator's Family Members) that reasonably appears to be related to the Investigator's Institutional Responsibilities:
 - With regard to any publicly traded entity, a Significant Financial Interest exists if the value of any remuneration received from the entity in the 12 months preceding the disclosure and the value of any equity interest in the entity as of the date of the disclosure, when aggregated, exceeds \$5,000. For purposes of this definition, remuneration includes salary and any payment for services not otherwise identified as salary (e.g. consulting fees, honoraria, paid authorship); and equity interest includes any stock, stock option, or other ownership interest, as determined through reference to public prices or other reasonable measures of fair market value;
 - With regard to any non-publicly traded entity, a Significant Financial Interest exists if the value of any remuneration received from the entity in the 12 months preceding the disclosure, when aggregated, exceeds \$5,000, or when the Investigator (or the Investigator's Family Members) holds any equity interest (e.g. stock, stock option, or other ownership interest); or

- Intellectual property rights and interests (e.g. patents, copyrights), upon receipt of income related to such rights and interests.
- (ii) Investigators also must disclose the occurrence of any reimbursed or sponsored travel (i.e. that which is paid on behalf of the Investigator and not reimbursed to the Investigator so that the exact monetary value may not be readily available), related to their Institutional Responsibilities; provided, however, that this disclosure requirement does not apply to travel that is reimbursed or sponsored by a federal, state or local government agency, an institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education. The disclosure must specify, at a minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination and the duration. The Institutional Official may determine if further information is needed to determine whether the travel constitutes a Financial Conflict of Interest.
- (iii) The term Significant Financial Interest does not include the items specified in 42 CFR 50.603 that are excluded from the definition of Significant Financial Interest, including, among others, salary or other remuneration paid by the University to the Investigator if the Investigator is currently employed or otherwise appointed by the University; income from investment vehicles, such as mutual funds and retirement accounts, as long as the Investigator does not directly control the investment decisions made in these vehicles; and income from seminars, lectures, or teaching engagements sponsored by a federal, state or local government agency, an institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education.
- h. University. University shall mean the University of San Diego.
- i. University Official. The University Official is an administrator in the Provost's office designated by the Vice President and Provost. The Vice President and Provost is authorized to designate an alternate University Official in the event that administrator is unable or unavailable to assume the responsibilities of the University Official under this policy.

3. Responsibility of Investigators

- a. Investigators on Externally-Funded Research projects are expected to identify and, when possible, avoid Financial Conflicts of Interest. Investigators must make all disclosures as required by this policy and any implementing procedures. Investigators also are expected to comply with the University's Individual Conflicts of Interest Policy with respect to any conflicts of interest that are covered by that policy, even if not covered by this Financial Conflicts of Interest Policy.

- b. Investigators are expected to cooperate in the review and management of any disclosed conflicts, and shall comply with the terms of any management plan implemented pursuant to this policy.
- c. Investigators are required to complete training on Financial Conflicts of Interest. (See Section 8 below.)
- d. If the Externally-Funded Research is carried out through a subrecipient (e.g. subcontractors or consortium members), the University will take reasonable steps to ensure that the subrecipient Investigator complies with this policy or the subrecipient's own financial conflicts of interest policy. Certifications shall be provided by the subrecipient to the extent required by 42 CFR 50.604(c).

4. Disclosure of Financial Conflicts of Interest

- a. All disclosures made under this policy shall be submitted to the University Official. The information provided in the disclosure must be complete, accurate, and may not be misleading.
- b. Each Investigator shall disclose the Investigator's Significant Financial Interests (and those of the Investigator's Family Members) no later than the time of the application for the Externally-Funded Research.
- c. Each Investigator shall submit an updated disclosure of Significant Financial Interests at least annually, in accordance with any specific time period prescribed by the University, during the period of the award. Such disclosure shall include any information that was not disclosed initially to the University under Section 4.b. or in a subsequent disclosure of Significant Financial Interests, and shall include updated information regarding any previously disclosed Significant Financial Interest.
- d. Each Investigator shall submit an updated disclosure of Significant Financial Interests within 30 days of discovering or acquiring a new Significant Financial Interest.

5. Review and Management of Financial Conflicts of Interest

- a. The University Official will determine whether an Investigator's Significant Financial Interest is related to Externally-Funded Research and, if so related, whether the Significant Financial Interest is a Financial Conflict of Interest.
 - (i) An Investigator's Significant Financial Interest is related to Externally-Funded Research when the University, through the University Official, reasonably determines that the Significant Financial Interest could be affected by the Externally-Funded Research or is in an entity whose Financial Interest could be affected by the research. Before making a determination, the University Official will provide the

Investigator with an opportunity to submit information regarding whether a Significant Financial Interest is related to the Externally-Funded Research.

- (ii) A Financial Conflict of Interest exists where the University, through the University Official, reasonably determines that the Significant Financial Interest could directly and significantly affect the design, conduct or reporting of Externally-Funded Research.
- b. The University, through the University Official, will take such actions as necessary to manage Financial Conflicts of Interest. Management of an identified Financial Conflict of Interest requires development and implementation of a management plan. The management plan will be developed and implemented before the University's expenditure of funds or, in the case of an ongoing project, within 60 days of the disclosure of a Significant Financial Interest that is determined to be a Financial Conflict of Interest. The management plan will specify the actions that have been, and shall be, taken to manage the Financial Conflict of Interest. Examples of conditions or restrictions that might be imposed to manage a Financial Conflict of Interest include, but are not limited to:
- (i) Public disclosure of Financial Conflicts of Interest;
 - (ii) For research projects involving human subjects research, disclosure of Financial Conflicts of Interest directly to participants;
 - (iii) Appointment of an independent monitor capable of taking measures to protect the design, conduct, and reporting of the research against bias resulting from the Financial Conflict of Interest;
 - (iv) Modification of the research plan;
 - (v) Change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the research;
 - (vi) Reduction or elimination of the Financial Interest; or
 - (vii) Severance of relationships that create the Financial Conflict of Interest.
- c. Whenever a Financial Conflict of Interest in PHS-funded research is not identified or managed in a timely manner, a retrospective review and, if appropriate, a mitigation report will be prepared and submitted to the extent required by 42 CFR Part 50.605(a)(3).

- d. Whenever the University implements a management plan under this policy, the University will monitor Investigator compliance with the management plan on an ongoing basis until the completion of the Externally-Funded Research project.

6. Public Access.

This policy and the disclosure of Investigator Financial Conflicts of Interest for PHS-funded research shall be available to the public to the extent required by 42 CFR Part 50.605(a)(5).

7. Reporting

The University will report Financial Conflicts of Interest for PHS-funded research to the extent required by 42 CFR Part 50.601 et seq.

The University may make conflict of interest disclosure forms, conflict management plans, and related information available to an agency or other outside party that provided funding for the Externally-Funded Research.

8. Training

Prior to engaging in any Externally-Funded Research at the University and at least every four years, each Investigator shall complete training as required by the University regarding Financial Conflicts of Interest. Training also will be required when the University revises its Financial Conflict of Interest policy or procedures in any manner that affects the requirements of Investigators; when an Investigator is new to the University; or when the University finds that an Investigator is not in compliance with the University's Financial Conflict of Interest policy or management plan.

9. Record Retention

Records of financial disclosures and any resulting action will be maintained by the University for at least three years from the date of submission of the final expenditures report or otherwise as required by 45 CFR 74.53 and 92.42.

10. Non-Compliance

Failure to comply with this policy and any implementing procedures may result in corrective action, as appropriate under the circumstances. Failure to comply includes but is not limited to the failure to file timely disclosures; filing incomplete, erroneous, or inaccurate disclosures; or failure to comply with prescribed procedures for managing or resolving conflicts of interest. The corrective action may range from verbal warnings up to and including termination from employment. Additional action may be required in the event of non-compliance involving PHS-funded research. (See, e.g. 45 CFR 50.606.) If termination of a faculty member is contemplated, the applicable rules governing dismissal for serious cause will be followed.

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