FINANCIAL CONFLICT OF INTEREST POLICY FOR INVESTIGATORS WITH PRIVATE INSTITUTION/NON-GOVERNMENTAL FUNDING 700U

I. Introduction

San Diego State University is generally supportive of appropriate consulting and other outside professional activities by its professional personnel (see Professional Activities, External (University Policy File, pp. 159-160). Indeed, the University recognizes that many such activities may enhance professional experience and complement campus activities. Consequently, the University does not seek to interfere with the legitimate outside interests of the faculty or other professional personnel. Such involvement, however, may lead to situations and circumstances which do, or reasonably appear to, conflict with: (a) the interests of the University; (b) the individual's primary commitment to his/her responsibilities for teaching, research and service at the University; or (c) the interests of certain external sponsors of their research or other educational activities at the University.

II. Policy Purpose & Scope

The purpose of this policy is to protect the integrity of research conducted at SDSU, as well as the integrity and credibility of researchers associated with the University. This Policy implements California regulations which require an investigator to disclose whether or not he or she has a direct or indirect financial interest in the project's sponsor. If the sponsor is a private organization/non-governmental entity, a Statement of Economic Interest (Form 700U) may be required. Disclosures of financial interest will be reviewed by the Conflict of Interest committee and it will be determined if the conflict can be appropriately managed, reduced, or eliminated.

III. Definitions

Conflict of Interest Committee:

The Conflict of Interest Committee is appointed by the President (or designee) with the recommendation of the University Research Council. The Committee shall consist of at least three (3) faculty representatives selected from the University Research Council, the Executive Director (or designee) of the SDSU Research Foundation, the Associate Vice President responsible for Human Resources (or designee) who shall be Chair, the Director of the Technology Transfer Office, and the Assistant Vice President of Research Support Services.

Investigator:
Investigator means the project director or principal investigator and any other person, regardless of title or position, who has responsibility, or shares responsibility with the Principal Investigator, for the design, conduct, or reporting of research funded by the PHS, or proposed for such funding. This includes but is not limited to individuals identified as Key Personnel in the contract or grant proposal. It may also include collaborators who are identified as consultants and/or subcontractors where the foregoing definition may apply.

Investment:
"Investment" means any financial interest in a business entity in which you, your spouse or registered domestic partner, or your dependent children have a direct, indirect, or beneficial interest totaling $2,000 or more. Reportable investments include stocks, bonds, warrants, and options, including those held in margin or brokerage accounts. (See Gov. Code Section 82034 and Regulation 18237.)

Income:
"Income" means a payment received, including but not limited to any salary, wage, advance, dividend, interest, rent, proceeds from any sale, gift, including any gift of food or beverage, loan forgiveness or payment of indebtedness received by the filer, reimbursement for expenses, per diem, or contribution to an insurance or pension program paid by any person other than an employer, and any community property interest in income of a spouse or registered domestic partner. Income also includes an outstanding loan.
Income of an individual also includes a pro rata share of any income of any business entity or trust in which the individual, spouse, or registered domestic partner owns directly, indirectly, or beneficially, a 10% interest or greater. Income includes your gross income and your community property interest in your spouse's or registered domestic partner's gross income totaling $500 or more. Gross income is the total amount of income before deducting expenses, losses, or taxes. (See Gov. Code Section 82030.)

Loan:
Loans received or outstanding are reportable if they total $500 or more from a single lender. Your community property interest in loans received by your spouse or registered domestic partner also must be reported. Loans from commercial lending institutions made in the lender's regular course of business on terms available to members of the public without regard to your official status are not reportable. (See Gov. Code Section 82030(a).

Gift:
A gift is anything of value for which you have not provided equal or greater consideration to the donor. A gift is reportable if its fair market value is $50 or more. In addition, multiple gifts totaling $50 or more received from a reportable source must be reported. It is the acceptance of a gift, not the ultimate use to which it is put, that imposes your reporting obligation. Therefore, you must report a gift even if you never used it or if you gave it away to another person. If the exact amount of a gift is not known, you must make a good faith estimate of the item's fair market value. Listing the value of a gift as "over $50" or "value unknown" is not adequate disclosure.

Financial Interest:
Financial interest means anything of monetary value, whether or not the value is readily ascertainable**.**

Financial Conflict of Interest:
For the purposes of this policy, financial conflict of interest (FCOI) means a financial interest that could directly and significantly affect the design, conduct, or reporting of research. A conflict exists when it has been determined that:

(a) an outside activity or economic interest undertaken or held by an Investigator (including economic interests of the Investigator's spouse/domestic partner and dependent children) does-- or appears to-- compete, interfere, or otherwise adversely affect the Investigator's professional obligations to the University, the SDSU Research Foundation and/or a designated external sponsor;

(b) when entities in which economic interests are held would be directly and significantly affected by the research or educational activities of the Investigator such that reasonable questions might be raised as to whether such actions are determined primarily by considerations of personal financial gain; or

(c) when a significant financial interest could directly and significantly affect the design, conduct or reporting of funded research or educational activities.

IV. 700U Requirements:

A. Investigators complete a training/education program:

1. Before engaging in research activities supported by private institutions/non- governmental agencies; and
2. Whenever an Investigator is not in compliance with this Policy or has failed to comply with a plan put in place to manage or mitigate a Financial Conflict of Interest

B. Investigators disclose Significant Financial Interests at the following times:

1. Initial Statement –The 700U must be submitted to the Office of Grants and Contracts before final acceptance of a contract, grant, or gift. The 700U shall indicate reportable investments in and positions with the sponsor as of the date of the offer of funding, and income and gifts received from the sponsor within 12 months prior to the date of the offer.
2. Interim Statement – The 700U must be filed within 30 days after funding is renewed and shall disclose reportable investments, income and business positions held or received during the project period between the date the initial statement was filed and the date the funding for the project was renewed.

V. Review and Evaluation of Research Investigator Financial Interest Disclosure Statements

Research Support Services will review submitted disclosures and, if necessary, addendums to determine whether the Outside Professional Activity or Financial Interest is related to Investigator's SDSU Responsibilities or presents an actual or perceived Conflict of Interest or Conflict of Commitment under this policy.

Based on information provided in the Disclosure and addendum, the COI Coordinator may determine that there is no reasonable basis on which to conclude that a project could directly and significantly affect the financial interest and that the financial interest is not likely to affect the design, conduct, or reporting of the project. In this case, a record will be made of the Reviewing Official's determination and the project can proceed without further review.

In the event that either the Investigator or the COI Coordinator concludes that a project might have a direct and significant impact on the financial interest and that the financial interest could affect the design, conduct or reporting of the project, the Disclosure and appropriate documentation shall be forwarded to the Conflict of Interest Committee for consideration. The same review process takes place when an Investigator files an Update form reporting a new, related financial interest.

The Committee shall review the information provided by the Investigator through the disclosure form and addendum statement, evaluate the disclosure to determine whether the financial interest could significantly affect the conduct or reporting of the project, and determine what, if any, conditions or restrictions should be imposed on the Investigator or research protocol in order to manage, reduce or eliminate conflicts that are identified. The Committee may also evaluate whether the financial interest has the potential to improperly influence financial expenditures, personnel decisions, or facilities usages, or has potential to limit or influence the teaching and research environment of the University. The Committee may consult with the Investigator, faculty, administrators, other University personnel or an outside ad hoc subject matter expert, as appropriate, in developing a plan to resolve any real or apparent conflict of interest issues.

The Committee shall report recommendations on all cases considered to the President, the Vice President for Research, the affected college Dean and the Research Foundation when conditions or restrictions are implemented to manage the potential conflict. An annual summary report shall also be provided to the University Research Council.

VI. Actions of the Conflict of Interest Committee

Acting in a timely manner so as not to unduly delay the conduct of the research, the Committee shall conclude that the University take one of the following actions: (1) approval of acceptance of the project award; (2) withdrawal of the proposal or disapproval of acceptance of the project award; or (3) approval of acceptance of the project award subject to implementation of recommendations for modifications in either the project proposal or in the external affiliations or economic interests of the Investigator. Recommended actions to resolve conflicts of interest may include but are not limited to the following:

- Public disclosure of significant financial Interests
- Monitoring of research by independent reviewers
- Modification of the research plan subject to sponsor approval
- Disqualification from participation in the portion of the research that would be affected by the significant financial interests
- Divestiture of significant financial interests
- Severance of relationships that create actual or potential conflicts

VII. Decision and Appeal Process

The conclusions of the Conflict of Interest Committee, along with any recommended modifications in the project or the significant financial interests of the Investigator shall be promptly communicated to the Investigator, the SDSU Research Foundation and the Vice President for Research. If the Committee proposes such modifications and the Investigator agrees with the conclusions of the Committee, the Investigator will provide the Committee with appropriate documentation sufficient to verify that any such modifications have been made. If the Investigator is dissatisfied with the conclusions of the Committee, the Investigator may appeal to the President. Acting on behalf of the President, the Vice President for Research may investigate and make appropriate recommendations to the President regarding the disposition of the matter. In such cases, the decision of the President shall be final.

VIII. Enforcement Mechanisms and Sanctions

The SDSU Research Foundation shall withhold access to awards from designated external sponsors when the disclosure statement has not been completed by the investigator or reviewed by the Committee. Grants and/or contracts designated for research purposes will not be available to the Investigator until the disclosure has been submitted and reviewed.

Alleged violations of the policy or procedures used to implement the policy shall be investigated by the Vice President for Research, who may, after consultation with the President or designee, suspend or terminate the research project or the Investigator's involvement in the research.

Substantive violations of this policy, such as instances of falsification or willful concealment of significant financial interests, or failure to implement or maintain necessary modifications required by the Conflict of Interest Committee and agreed to by the Investigator, may also constitute violations of the SDSU Policy on Integrity in Research and Scholarship (University Policy File, Page 110). In such cases, the Vice President for Research may initiate procedures for investigation and recommend possible imposition of sanctions by the President of the University as outlined therein.

In any cases in which it has been determined that a project of clinical research whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment has been designed, conducted or reported by an Investigator with a conflicting interest that was not disclosed or managed as required by this research Investigator conflict of interest policy, the University will require disclosure of the conflicting interest in each public presentation of the results of the research.

IX. Maintenance of Records

Research Support Services shall maintain records of all disclosure statements and of all actions taken to resolve conflicts of interest for at least three (3) years beyond the date of submission of the award's final expenditure report. Records relating to unfunded projects need not be retained. Copies of all financial disclosures of University employees may also be kept by The Center for Human Resources in a manner consistent with other conflict or disclosure statements by University personnel. The SDSU Research Foundation may also retain copies of such records for its employees.

X. Training

As required by CSU, all investigators as defined in this policy on private institution/non-governmental grants and sub-recipient awards will be required to complete CSU's Conflict of Interest training prior to beginning work on private institution/non-governmental agency funded research.

XI. Review and revision of policy

This policy will be reviewed annually by the Conflict of Interest committee. The committee shall develop and, as required, amend specific guidelines for the implementation of the provisions of this policy. These guidelines will be submitted for approval to the Vice President for R&I.

Contact Information

Conflict of Interest Committee
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POLICY EFFECTIVE DATE: November 22st, 2023