

FINANCIAL CONFLICT OF INTEREST POLICY FOR INVESTIGATORS SPONSORED BY NSF

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. 84-85)). 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

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 is intended to serve as a guide to faculty and other employees with principal responsibility for research projects funded by NSF and to establish procedures to be followed in avoiding and/or resolving actual and potential conflicts of interest pertaining to such projects.

III. Definitions

A. **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 Director of the Division of Research Affairs.

B. **Investigator:**

Investigator means the project director or principal investigator and any other person, regardless of title or position, who has, or shares, independent responsibility for the design, conduct, or reporting of research funded or proposed for funding by NSF. In this context, "Investigator" also includes the investigator's spouse/domestic partner and dependent children.

C. **Outside Activity:**

Any professional or remunerative activity undertaken by SDSU faculty or other professional personnel that is outside the scope of their designated University duties. Refer to policy on Professional Activities, External ([University Policy File](#), pp.84-85).

D. Financial Interest:

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

E. Financial Conflict of Interest:

For the purposes of this policy, financial conflict of interest (FCOI) means a significant 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.

F. Institutional Responsibilities:

Institutional responsibilities means an Investigator's professional responsibilities on behalf of the Institution, and as defined by the Institution in its policy on financial conflicts of interest, which may include for example: activities such as research, research consultation, teaching, professional practice, institutional committee memberships, and service on panels such as Institutional Review Boards or Data and Safety Monitoring Boards.

G. Required Financial Disclosure:

Disclosure of significant financial interests means an Investigator's disclosure of significant financial interests to an Institution.

H. Significant Financial Interest:

Significant financial interests are involved and must be disclosed where one or more of the following financial interests of the investigator (and those of the investigator's spouse/domestic partner or dependent children) reasonably appears to be related to the investigator's Institutional responsibilities:

- A *significant financial interest* exists if an equity interest that, when aggregated for the investigator and the investigator's spouse/domestic partner and dependent children, exceeds \$10,000 in value as determined through reference to public prices or other reasonable measures of market value, and represent more than a 5% ownership interest in any single entity
- A *significant financial interest* exists when salary, royalties or other payments that, when aggregated for the investigator and the investigator's spouse/domestic partner of dependent children, have exceeded or are expected to exceed \$10,000 during any immediately preceding or following 12 month period.

- For National Science Foundation (NSF), significant financial interest **does not** include:
 - Salary, royalties or other remuneration from the applicant Institution
 - Any ownership interest in the Institution, if the Institution is an applicant under the Small Business Innovation Program or Small Business Technology Transfer Program
 - Income from seminars, lectures, or teaching engagements sponsored by public or nonprofit entities
 - Income from service on advisory committees or review panels for public or nonprofit entities
 - Equity interest and/or salary, royalty and other payments do not exceed the thresholds in the section regarding NSF immediately above

IV. Disclosure Requirement for Investigators

Each SDSU Investigator (as defined above) who submits, renews or participates in a proposal in which NSF funds are sought must file the appropriate financial disclosure statement at the time of the submission of the grant proposal. Such disclosures must be updated at the time of the award (if more than 90 days from initial disclosure) and then on an annual basis during the period of the award and within 30 days of new reportable significant financial interests. New investigators must complete a disclosure before joining an ongoing project.

The Investigator may also be advised by a SDSU Research Foundation program administrator of the requirement to file a final disclosure statement upon the completion of a contract or grant, or of complete expenditure of funds. The investigator is ultimately responsible for compliance with the reporting requirements. In addition, the SDSU Research Foundation will submit a quarterly report to the Division of Research Affairs listing projects that have ended.

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

The SDSU Research Foundation will forward complete disclosures to the Division of Research Affairs for administrative review. If a disclosure reveals a significant financial interest based on defined criteria and determined to be related to the proposed research activity, the Investigator will be asked to complete an addendum to the disclosure for use in further evaluation. Copies of the completed disclosure, the addendum, and proposal will then be forwarded to members of the Conflict of Interest Committee for review by the convened Committee.

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 or other University personnel, 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 and the affected college Dean when conditions or restrictions are implemented to manage the potential conflict. An annual summary report shall also be provided to the University Research Council. The Committee shall also 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 Research.

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 57). 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. Notification of External Sponsor

Initial, annual (i.e. ongoing) and revised FCOI reports must be made to the external sponsor at the following times:

1. Prior to the expenditure of funds;
2. Within 60 days of the identification of an Investigator who is newly participating in the project;
3. Within 60 days for new, or newly identified, FCOIs for existing Investigators;
4. At least annually (at the same time as when the University is required to submit the annual progress report, multi-year progress report, if applicable, or at the time of extension) to provide the status of the FCOI and any changes to the management plan, if applicable, until the completion of the project;
5. Following a retrospective review to update a previously submitted report, if appropriate.

When identified conflicts of interest are eliminated before research funds are expended, no report need be submitted.

If a Significant Financial Interest (SFI) is identified during the course of an ongoing project that was not previously disclosed or reviewed, the Conflict of Interest Committee will review the SFI within sixty (60) days to determine whether it is related to research activities and whether a FCOI exists. If a FCOI is identified after such a review, a management plan must be implemented, at least on an interim basis (see section VI).

If the University determines that a FCOI exists that was not previously identified or managed in a timely manner, the University will complete a retrospective review of the Investigators activities. This retrospective review must occur (or “be completed”) within 120 days of the determination of non-compliance. The purpose of this retrospective review is to determine if the ongoing research activity was biased in its design, conduct or reporting.

Based on the results of the retrospective review, the previously submitted FCOI report must be updated to specify the actions that the University will take to manage the identified FCOI. If bias was found during the retrospective review, the University will promptly notify the external funding source and will draft a mitigation report that at a minimum documents the key elements of the retrospective review, describes the impact of the bias on the research, and outlines the institution’s plans to eliminate or mitigate the effect of the bias.

XI. Maintenance of Records

The Division of Research Affairs 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, or until the resolution of any NSF action involving those records, whichever is longer. 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.

XII. Training

There is no training requirement by NSF, but the Institution does provide on-going training about conflicts of interest, and investigators are encouraged to attend.

Contact Information

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